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No.

In the Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,
F/K/A LEESBURG FAMILY MEDICINE,
PETITIONER,

v.

UNITED STATES OF AMERICA *EX. REL.* KARYN L. WALKER,
RESPONDENT.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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July 2006

QUESTION PRESENTED

Whether liability under the civil False Claims Act, 31 U.S.C. §§ 3729-3733, can be based on a reasonable interpretation of an ambiguous regulation or contractual provision?

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner R & F Properties of Lake County, Inc., has no parent corporation. No publicly held company owns 10 percent or more of the stock of R & F Properties of Lake County, Inc.

The only identifiable legal entity related to R & F Properties of Lake County, Inc. is Leesburg Family Medicine, P.L., f/k/a Robinson & Foster, P.L.

TABLE OF CONTENTS

Page

QUESTION PRESENTED..... i

RULE 29.6 CORPORATE DISCLOSURE STATEMENT..... ii

TABLE OF AUTHORITIES..... v

OPINIONS BELOW..... 1

JURISDICTION..... 1

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED..... 1

STATEMENT OF THE CASE..... 2

REASONS FOR GRANTING THE PETITION..... 7

I. THE DECISION BELOW DEEPENS EXISTING CONFLICT AND CONFUSION AMONG THE CIRCUIT COURTS..... 9

A. The Eleventh Circuit's Decision Conflicts With Other Circuit Courts Regarding Whether A Civil False Claims Act Lawsuit Can Be Based On A Reasonable Interpretation Of An Ambiguous Regulation Or Contract..... 9

B. The Eleventh Circuit's Decision Conflicts With Numerous Criminal False Claims Act Cases..... 16

II. THE DECISION BELOW VIOLATES BASIC CONSTITUTIONAL AND COMMON LAW PRINCIPLES 21

A. The Eleventh Circuit's Decision Is Contrary To The Due Process Clause 22

B. The Eleventh Circuit's Decision Is Contrary To The Rule of Lenity 25

C. Eleventh Circuit's Decision Is Contrary To The Principle Of Interpreting An Ambiguous Provision Against Its Drafter 26

III. THE QUESTION PRESENTED IN THIS CASE IS FAR-REACHING AND OF EXCEPTIONAL IMPORTANCE 28

CONCLUSION 30

TABLE OF AUTHORITIES

Cases

Ashman v. Barrows,
438 F.3d 781 (7th Cir 2006) 14

Commercial Contractors, Inc. v. United States,
154 F.3d 1357 (Fed. Cir. 1998) 13

Cook County v. United States ex rel. Chandler,
538 U.S. 119 (2003) 22

Crandon v. United States,
494 U.S. 152 (1990) 26

Gates & Fox Co. v. OSHRC,
790 F.2d 154 (D.C. Cir. 1986) 23-24

Gelb v. Bd. of Elections
224 F.3d 149 (2d Cir. 2000) 14

General Elec. Co. v. EPA,
53 F.3d 1324 (D.C. Cir. 1995) 23, 24

Grayned v. City of Rockford,
408 U.S. 104 (1972) 23

Hagood v. Sonoma County Water Agency,
81 F.3d 1465 (9th Cir. 1996) 12

Hays v. Hoffman,
325 F.3d 982 (8th Cir. 2003) 22

Justofin v. Metropolitan Life Ins. Co.,
372 F.3d 517 (3d Cir. 2004) 14

Luckey v. Baxter Healthcare Corp.,
2 F. Supp. 2d 1034 (N.D. Ill. 1998)
aff'd, 183 F.3d 730 (7th Cir. 1999) 5, 12

Minnesota Ass'n. of Nurse Anesthetists v. Allina Health Sys. Corp., 276 F.3d 1032 (8th Cir. 2002) 12

Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306 (1950) 23

Olson v. Mellon, 4 F. Supp. 947 (W.D. Penn. 1933), *aff'd sub nom United States ex rel. Knight v. Mellon*, 71 F.2d 1021 (3rd Cir. 1934) 17

Rehab. Ass'n v. Kozlowski, 42 F.3d 1444 (4th Cir. 1994) 28-29

Rollins Envtl. Servs., Inc. v. EPA, 937 F.2d 649 (D.C. Cir. 1991) 24

Satellite Broad. Co. v. FCC, 824 F.2d 1 (D.C. Cir. 1987) 23

Sullivan v. Stroop, 496 U.S. 478 (1990) 18

Texas Indus., Inc. v. Radcliff Materials, Inc., 451 U.S. 630 (1981) 21

Trinity Broad. of Fla., Inc. v. FEC, 211 F.3d 618 (D.C. Cir. 2000) 24

Tyger Constr. Co. v. United States, 28 Fed. Cl. 35 (1993) 12

UMC Elecs. Co. v. United States, 43 Fed. Cl. 776 (1999) 19

United States ex rel. Dunleavy v. County of Delaware, 279 F.3d 219 (3rd Cir. 2002), *vacated*, 538 U.S. 918 (2003) 22

United States ex rel. Grynberg v. Praxair, Inc.,
207 F. Supp. 2d 1163 (D. Colo. 2001),
aff'd in part, rev'd in part, 389 F.3d 1038
(10th Cir. 2004) 29

United States ex rel. Lamers v. City of Green Bay,
168 F.3d 1013 (7th Cir. 1999) 11

United States ex rel. Local 342 Plumbers & Steamfitters v. Dan Caputo Co., 321 F.3d 926 (9th Cir. 2003) 14

United States ex rel. Marcus v. Hess,
317 U.S. 537 (1943) 18, 19

United States ex rel. Morton v. A Plus Benefits, Inc.,
139 Fed. Appx. 980 (10th Cir. 2005) 11

United States ex rel. Oliver v. Parsons Co.,
195 F.3d 457 (9th Cir. 1999) 11

United States ex rel. Swafford v. Borgess Med. Ctr.,
24 Fed. Appx. 491 (6th Cir. 2001) 11

United States v. Anderson,
579 F.2d 455 (8th Cir. 1978) 20

United States v. Barsanti,
943 F.2d 428 (4th Cir. 1991) 20-21

United States v. Bass,
404 U.S. 336 (1971) 26

United States v. Burns,
162 F.3d 840 (5th Cir. 1998) 19

United States v. Cripps,
460 F. Supp. 969 (E.D. Mich. 1978) 18

United States v. Dale,
991 F.2d 819 (D.C. Cir. 1993) 21

United States v. Data Translation, Inc.,
984 F.2d 1256 (1st Cir. 1992) 29

United States v. Estate of Rogers,
No. 1:97CV461, 2001 WL 818160 (E.D. Tenn. June 28, 2001) 13

United States v. Hoechst Celanese Corp.,
128 F.3d 216 (4th Cir.1997) 23

United States v. Hughes Helicopter Co.,
No. CV 89-5760SVN, 1993 WL 841192 (C.D. Cal. Aug. 25, 1993)
aff'd 71 F.3d 321 (9th Cir. 1995) 19

United States v. Johnson,
937 F.2d 392 (8th Cir. 1991) 20

United States v. Kozminiski,
487 U.S. 931 (1988) 25, 26

United States v. Lanier,
520 U.S. 259 (1997) 22, 25

United States v. Mackby,
261 F.3d 821 (9th Cir. 2001). 22

United States v. Migliaccio,
34 F.3d 1517 (10th Cir. 1994) 20

United States v. Napco Int'l, Inc.,
835 F. Supp. 493 (D. Minn. 1993) 12

United States v. Newport News Shipbuilding, Inc.,
276 F. Supp. 2d 539 (E.D. Va. 2003) 15-16

United States v. Race,
632 F.2d 1114 (4th Cir. 1980) 19, 20

United States v. Seckinger,
397 U.S. 203 (1970) 26, 27

United States v. Southland Mgmt. Corp.,
326 F.3d 669 (5th Cir. 2003) 12, 19

United States v. St. Luke's Subacute Hosp., & Nursing Centre, Inc., No. 00-1976, 2004 WL 2905237 (N.D. Cal. Dec. 16, 2004) 18

United States v. Szilvagyi,
398 F. Supp. 2d 842 (E.D. Mich. 2005) 18

United States v. Taber Extrusions, LP,
341 F.3d 843 (8th Cir. 2003) 14

United States v. Thompson/Center Arms Co.,
504 U.S. 505 (1992) 25-26

United States v. Turner Constr. Co.,
819 F.2d 283 (Fed. Cir. 1987) 27

United States v. Whiteside,
285 F.3d 1345 (11th Cir. 2002) 20

Vermont Agency of Natural Res. v. United States ex rel. Stevens,
529 U.S. 765 (2000) 8, 21

Washington Legal Found. v. Henney,
128 F. Supp. 2d 11 (D.D.C. 2000) 29

Whalen v. United States,
445 U.S. 684 (1980) 25

X Corp. v. Doe,
816 F. Supp. 1086 (E.D. Va. 1993) 29

Constitution, statutes, and regulations:

U.S. Const. amend. V 1

18 U.S.C.:

Section 286 17

Section 287 ..... 1, 16, 17, 19

Section 1001 ..... 1, 17

Section 1002 17

28 U.S.C. § 1254(1) 1

31 U.S.C.:

Section 3729 ..... 1, 2

Section 3729(a) 19, 20

Section 3729(b) 15

Section 3730 ..... 1, 2

Section 3730(b) 4

Section 3730(d) 4

Section 3731 ..... 1, 2

Section 3731(d) 18

Section 3732 ..... 1, 2

Section 3733 ..... 1, 2,

42 C.F.R.

Section 410.10 ..... 1, 2

Section 410.26 ..... 1, 2, 24, 26

Section 410.32(b)(3)(ii) 2

Section 489.11 27

Miscellaneous:

AMERICAN MEDICAL ASSOCIATION, *Rethinking Medicare: Solutions for Medicare's Short- and Long-term Problems*, (2002) 28

Daniel Yi, Tenet to Pay $900 Million to Settle U.S. Allegations, L.A. TIMES, Jun. 30, 2006, at C1. 30

U.S. Gov't Accountability Office, *Information on False Claims Act Litigation* (2006) 7

Peter Pae, *Northrop Settles Two U.S. Suits*, L.A. TIMES, Aug. 27, 2003, § 3, at 2 15

Press Release, Eric Holder, Deputy Attorney General (Mar. 31, 2000) 7

Press Release, Department of Justice, DOJ to Hold Briefing on the Use of False Claims Act in Health Care Fraud Cases (Apr. 23, 1998) 7

S. REP. No. 345, 99th Cong., 2d Sess. *reprinted in* 1986 U.S.C.C.A.N. 5266 17

PETITION FOR A WRIT OF CERTIORARI

Petitioner R&F Properties of Lake County, Inc., f/k/a Leesburg Family Medicine, respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Eleventh Circuit in this case.

OPINIONS BELOW

The opinion of the Eleventh Circuit (Pet. App. 1a-19a) is reported at 433 F.3d 1349. The order of the Eleventh Circuit denying rehearing and rehearing *en banc* (Pet. App., 37a) is unreported. The opinion of the district court (Pet. App. 20a-36a) also is unreported.

JURISDICTION

The judgment of the court of appeals was entered on December 30, 2005. A petition for rehearing was denied on March 31, 2006. Justice Thomas extended the time to file this petition up to and including July 29, 2006. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The Fifth Amendment to the United States Constitution provides that no person shall be deprived of "property without due process of law." U.S. Const. amend. V.

This case involves the civil False Claims Act, 31 U.S.C. §§ 3729-3733 (2006). It also involves the criminal false claims and false statement statutes, 18 U.S.C. §§ 287, 1001 (2006). In addition, it involves various Medicare

regulations, 42 C.F.R. §§ 410.10, 410.26 (2006). These relevant statutory and regulatory provisions are set forth in the Appendix to the petition, Pet. App. 38a-59a.

STATEMENT OF THE CASE

Petitioner R&F Properties of Lake County, Inc. ("R&F"), formerly known as Leesburg Family Medicine, is a family medical practice of five physicians with offices in Leesburg and Lady Lake, Florida. A majority of R&F's patients are covered by Medicare, a federally funded health insurance program. Respondent Karyn L. Walker ("Walker") worked as a nurse practitioner for R&F from 1997 to 1999.

On May 6, 2002, Walker filed a one-count complaint under seal in the United States District Court for the Middle District of Florida pursuant to the *qui tam* provisions of the civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733 (2006). Walker alleged that R&F improperly billed the United States for her nurse practitioner services in violation of the FCA. This case comes to the Court from the United States Court for Appeals for the Eleventh Circuit's reversal of a grant of summary judgment for Petitioner R&F.

Under Medicare Part B, a nurse practitioner can be billed in one of two ways. The nurse practitioner services can be billed to a patient under the nurse practitioner's Unique Provider Identification Number ("UPIN"). Alternatively, the services can be billed under the physician's UPIN as "incident to the service of a physician." 42 C.F.R. § 410.10, 410.26 (2006). During Walker's tenure at R&F, the Medicare regulations supplied no further definition of the phrase "incident to the service of a physician."[1] If the nurse

[1] An amended version of the Medicare regulations that became effective on January 1, 2002, clarified the "under the direct supervision of the physician" requirement by providing that direct supervision requires a

practitioner is billed under the physician's UPIN, the reimbursement is approximately 15% higher than if the nurse's UPIN is used.

At times during evenings and weekends, Walker provided services to patients when no R&F physician was physically present in the office. R&F's policy was to bill for these services under the physician's UPIN number because the nurse practitioner worked under the general supervision of the physicians and the physicians were immediately available via telephone or beeper to discuss a case with the nurse practitioner. Walker alleged that R&F knowingly submitted to the United States false and fraudulent claims for Medicare reimbursement by billing Walker's services as "incident to" a physician services even though on many occasions a physician was not on site and Walker would see new patients and make initial diagnoses and treatment plans.[2]

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physician to be present in the office suite. 42 C.F.R. §§ 410.26, 410.32(b)(3)(ii)(2006). However, this clarifying regulation was issued more than two years after Walker's employment with R&F terminated.

[2] The Medicare insurance claim form that R&F used to submit claims for reimbursement to the United States, Health Insurance Claim Form RRB-1500 ("HCFA-1500"), contains a certification reading:

> I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.

The HCFA-1500 form states that, for services to be considered as "incident" to a physician's professional service, (1) they must be rendered under the physician's immediate personal supervision by his/her employee, (2) they must be an integral, although incidental part of a covered physician's service, (3) they must be of kinds commonly

The United States declined to intervene in Walker's lawsuit, and the complaint was unsealed. Under the *qui tam* provisions of the FCA, Walker continued to prosecute her allegations that R&F defrauded the United States in its charging of nurse practitioner services to Medicare.[3]

On October 7, 2004, the federal district court granted R&F's motion for summary judgment on the ground that plaintiff Walker could not present sufficient evidence that R&F's claims were false or fraudulent. Pet. App. 33a-35a. The court's opinion began by noting that the "penal nature of the False Claims Act requires careful scrutiny of any alleged misconduct under the statute." *Id.* at 25a. The district court then analyzed whether R&F's claims were legally false for billing nurse practitioner services as "incident to the services of a physician" when the physician was available via beeper, fax or phone but not physically in the office. The court looked to the statutes and regulations in place during Walker's tenure at R&F between 1997 and 1999 and found that "neither the Medicare statutes nor the regulations provided much guidance as to the level of supervision required in order to bill the services of a nurse practitioner or physician assistant as 'incident to.'" *Id.* at 27a.

The district court rejected Walker's argument that R&F submitted false claims because of the definition of "incident to" provided in the Medicare Carriers Manual. *Id.* at 27a-32a. The court noted that the manual, unlike a statute

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furnished in physician's offices, and (4) the services of nonphysicians must be included on the bills. The HCFA form did not mention a physician being present in the office suite.

[3] The FCA allows the *qui tam* relator to prosecute the action with or without the participation of the United States. 31 U.S.C. § 3730(b)-(c) (2006). The relator shares in between 15 and 25 percent of any recovery of damages and penalties if the United States intervenes and between 25 and 30 percent if the United States does not intervene. *Id.* at § 3730(d).

or regulation, does not have the force and effect of law.[4] The district court's opinion stated that "[w]hen statutes and regulations forming the basis of the Plaintiff's claims under the False Claims Act are ambiguous, the Plaintiff has the burden of proving that the statements made by the Defendant in presenting its claim for reimbursement were unreasonable." *Id.* at 34a, n.38 (citing *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1049 (N.D. Ill. 1998), *aff'd*, 183 F.3d 730 (7th Cir. 1999)). The Court therefore granted the motion for summary judgment and dismissed the Complaint against R&F, ruling that Walker "failed to present sufficient evidence that [R&F's] interpretation of the terms, that it was appropriate to have a physician immediately available by phone while treating patients or for nonphysicians to change treatment plans or offer diagnoses under the supervision of a physician, contravened the requirements of the [HCFA] form or the Medicare statutes and regulations, thus violating the False Claims Act." *Id.* at 34a.

The United States Court of Appeals for the Eleventh Circuit reversed. The circuit court agreed with the trial court that the regulatory language that Walker contended R&F violated when submitting its reimbursement claims was ambiguous. *Id.* at 12a. However, the circuit court concluded that this ambiguity did not preclude a finding of FCA liability against R&F. *Id.* According to the Eleventh Circuit, "We agree that the regulatory language in effect until January 1, 2002 was ambiguous. But we disagree as to the legal significance of that ambiguity." *Id.*

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[4] The district court noted that there was no evidence that R&F agreed to comply with this manual – or any other Medicare training materials or publications – in order to receive payment from the Government. *Id.* at 32a. The court explained that the manual operates as a guideline for carriers – private companies that contract with Medicare to pay Part B bills – not providers like R&F; "the Carriers Manual is intended to instruct carriers as to whether to pay a claim and is not routinely provided to physicians." *Id.* at 30a-31a.

Even though the "incident to the service of a physician" language allegedly violated by R&F's Medicare claims was admittedly ambiguous, the Eleventh Circuit allowed Walker's FCA lawsuit to go forward. The Eleventh Circuit analyzed whether "at least some of these sources" of evidence provided by Walker would support her reading of the disputed regulatory language. *Id.* at 12a. The circuit court focused on the provisions of the Medicare Carrier's Manual, Medicare bulletins, seminar programs and expert testimony offered by Walker to support her interpretation of the "incident to" language. *Id.* at 12a-16a. The court acknowledged that none of these manuals, guidelines or other documents had the force of law. Nevertheless, the circuit court concluded that the various documents offered by Walker, "taken together," were sufficient support for her interpretation of the regulations to "raise an issue of fact" as to the falsity of R&F's reimbursement claims to Medicare. *Id.* at 16a.

Consequently, the Eleventh Circuit reversed the grant of summary judgment for defendant.[5]

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[5] The Eleventh Circuit also noted that a small subset of the false claims alleged by Walker to have been submitted occurred after January 1, 2002. *Id.* at 11a. These post-January 1, 2002 submissions would be covered by the amendments to the Medicare regulations that explicitly defined "incident to the service of a physician." *Id.* As a result, the appeals court ruled that these post-January 1, 2002 claims survived dismissal. In addition, the circuit court's decision addressed an unrelated discovery issue. *Id.* at 16a-18a. R&F's petition for certiorari does not seek review on the decisions below relating to claims for reimbursement filed post-January 1, 2002 or the discovery issue.

REASONS FOR GRANTING THE PETITION

The civil False Claims Act is described by the United States as its primary means of combating government contract fraud.[6] With treble damages and penalties of $5,500 to $11,000 per false claim, the FCA is a powerful tool for punishing false claims to the United States. In addition, the Act's unique *qui tam* provisions allow private whistleblowers to prosecute these actions and receive between 15% and 30% of any recovery achieved on behalf of the United States. Not surprisingly, FCA actions have proliferated, with almost 10,000 FCA cases filed since 1986 and settlements and judgments totaling more than $15 billion.[7]

Yet, the FCA also is subject to misuse. In bringing lawsuits under the FCA, plaintiffs have been able to take advantage of the complicated nature of the regulations and contracts involved in government programs. The regulations governing Medicare and Medicaid, drug pricing and marketing, defense contractor cost accounting, and natural resource leasing are exceedingly complex. FCA plaintiffs have seized upon ambiguities and legitimate disputes over interpretation to create allegations of fraud against government contractors. In many instances, FCA plaintiffs have been able to extract large settlements in lawsuits alleging that defendant violated an admittedly ambiguous regulation or contract.

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[6] Press Release, Eric Holder, Deputy Attorney General (Mar. 31, 2000), *available at* http://www.usdoj.gov/opa/pr/2000/March/159dag.htm (last visited June 27, 2006); Press Release, Department of Justice, DOJ to Hold Briefing on the Use of False Claims Act in Health Care Fraud Cases (Apr. 23, 1998), *available at* http://www.usdoj.gov/opa/pr/1998/April/194 .htm.html (last visited June 27, 2006).

[7] U.S. Gov't Accountability Office, *Information on False Claims Act Litigation* 5, 25 (2006), *available at* http://www.gao.gov/new.items/d06320r.pdf.

The Eleventh Circuit's decision below presents this problem of FCA cases arising from ambiguous government regulations or contracts. This petition for certiorari squarely raises the issue of whether an FCA case should be allowed to go forward where it is based on the defendant's reasonable interpretation of an admittedly ambiguous regulation or contract. This is an important issue on which the lower courts are in disarray. The Eleventh Circuit below, along with other lower courts, have allowed FCA cases to go forward even where the regulation or contract allegedly violated was ambiguous and the defendant's interpretation was reasonable. Other circuit courts faced with FCA cases based on alleged violations of ambiguous regulations or contracts have reached different results, dismissing on the grounds that a dispute as to regulatory interpretation cannot implicate FCA liability. Yet other courts have analyzed FCA cases involving ambiguous regulations or contracts by looking to the state of mind of the defendant or whether the defendant's interpretation was plausible. Furthermore, the well-established case law in criminal FCA and false statements cases – where the court is interpreting the same general statutory language – is that no liability can attach where the defendant relied on a reasonable interpretation of an ambiguous regulation or contract. Thus, this petition should be granted in order to resolve the confusion in the lower courts regarding whether an FCA case can be based on a reasonable interpretation of an ambiguous regulation or contract.

Moreover, it violates well-accepted constitutional and common law principles to allow FCA cases to go forward based on ambiguous regulations or contracts. In light of the FCA's onerous treble damages and penalties, this Court has recognized that the FCA is "essentially punitive in nature." *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-85 (2000). Due Process requires that, before imposing such a punishment, a person must

receive fair warning that her conduct is unlawful. Where the regulation or contract allegedly violated is ambiguous, the fair notice required by due process is clearly lacking. Similarly, the rule of lenity is applicable here since the government is seeking to impose punitive sanctions in the form of treble damages and hefty penalties for violation of an ambiguous regulation. In such circumstances, the rule of lenity requires that the ambiguity be resolved in favor of the defendant and the FCA action be dismissed. Furthermore, the doctrine that an ambiguous provision should be construed against the drafter also compels dismissal here. The government should not be allowed to benefit from ambiguities in regulations and contracts that the government drafted, and therefore FCA lawsuits (where the government is the primary beneficiary of any damages or penalties) should not go forward based on alleged violations of ambiguous regulations or contracts.

I. THE DECISION BELOW DEEPENS EXISTING CONFLICT AND CONFUSION AMONG THE CIRCUIT COURTS

A. The Eleventh Circuit's Decision Conflicts With Other Circuit Courts Regarding Whether A Civil False Claims Act Lawsuit Can Be Based On A Reasonable Interpretation Of An Ambiguous Regulation Or Contract

Supreme Court review is necessary to resolve conflict and confusion in the lower courts regarding whether, and under what circumstances, an alleged failure to comply with an ambiguous regulation or contract can serve as the basis for a FCA violation. The courts of appeals have reached different results when confronted with this fundamental question.

The Eleventh Circuit permits this FCA action to go forward against R&F, despite there being no dispute that the regulation allegedly violated was ambiguous and that R&F's interpretation of the ambiguous regulation was reasonable. The Eleventh Circuit expressly declared that the regulation was ambiguous during the relevant time period but held that this ambiguity did not preclude an FCA action based on the ambiguous regulation: "*We agree that the regulatory language in effect until January 1, 2002 was ambiguous. But we disagree as to the legal significance of that ambiguity.*" Pet. App. 12a (emphasis added). The Eleventh Circuit later emphasized this point of divergence from the district court's analysis leading to dismissal:

> [T]he district court found that the regulatory language that Walker claimed was violated when [R&F] submitted its claims was ambiguous and therefore could not, as a matter of law, serve as the predicate for a false claims action. We find error in the district court's reasoning.

Id. at 11a.

The Eleventh Circuit never attempted to challenge the district court's ruling by arguing that R&F's interpretation of the ambiguous regulation was somehow unreasonable. In fact, the circuit court never evaluated or discussed whether R&F's understanding of the "incident to" provision was reasonable. Instead, the Eleventh Circuit looked to whether the *plaintiff* had put forward sufficient evidence to support her interpretation of the regulation in question, with all inferences taken in her favor. Although the circuit court concludes that Walker's evidence, taken together and with all favorable inferences, created a material issue regarding the correct

interpretation of the ambiguous regulation, it nowhere disputed the reasonableness of R&F's interpretation.

The Eleventh Circuit's decision holds that a defendant's reasonable interpretation of an ambiguous regulation does not preclude an FCA action. Under the decision below, an FCA action survives as long as the plaintiff can come up with some support for her interpretation of the ambiguous regulation on which the FCA violation is based. At least one other circuit court has appeared to adopt a similarly liberal view allowing plaintiffs to go forward with FCA allegations based on violations of ambiguous regulations or contracts even where the defendant's interpretation is reasonable. *See United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 460 (9th Cir. 1999) (reversing trial court's ruling that a reasonable interpretation precludes liability under FCA; "[w]e hold that the district court erred in applying a 'reasonable interpretation' approach to determining falsity under the Act . . . ").

Other lower courts have adopted the diametrically opposite approach to ambiguity, emphasizing that the FCA was not intended to punish disputes over regulatory or contractual interpretations. These courts have followed the general rule that fraud cannot be predicated on a mere expression of opinion or legal dispute. *See, e.g.*, *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed. Appx. 980, 984 (10th Cir. 2005) ("Expression of a legal opinion, in this case depending, as it does, on the resolution of two sets of inherently ambiguous determinations by defendants, cannot form the basis for an FCA claim."); *United States ex rel. Swafford v. Borgess Med. Ctr.*, 24 Fed. Appx. 491, 491 (6th Cir. 2001) ("Disputes as to interpretation of regulations do not implicate False Claims Act liability."); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[I]mprecise statements or differences in interpretation growing out of a disputed legal question are similarly not

false under the FCA."); *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1479 (9th Cir. 1996) (Defendant "took advantage of a disputed legal issue. This, as we have previously held, is not enough."); *Luckey v. Baxter Healthcare Corp.*, 2 F. Supp. 2d 1034, 1049 (N.D. Ill. 1998) (granting summary judgment for defendant because plaintiff's alleged regulatory violation "suffer[s] the fatal flaw of ambiguity.");[8] *Tyger Constr. Co. v. United States*, 28 Fed. Cl. 35, 56 (1993) (noting that FCA liability will not attach for a statement relating to contract term that is incapable of precise definition; "Indication is absent that Congress intended to penalize good faith disputes over contract liability.").[9]

Some lower courts have focused on the defendant's intent, concluding that the defendant's knowledge relating to the ambiguous regulation is central for determining FCA liability. In *Minnesota Association of Nurse Anesthetists v. Allina Health Systems*, 276 F.3d 1032 (8th Cir. 2002), the Eighth Circuit addressed a trial court decision granting summary judgment for defendant based on the ambiguity in the Medicare regulations. The Eighth Circuit reversed because it found a question of fact as to the state of mind of the defendants. According to that circuit court, "[i]f a

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[8] The *Luckey* court relied on the decision in *United States v. Napco Int'l. Inc.*, 835 F. Supp. 493, 497-98 (D. Minn. 1993). In *Napco*, "the court held that ambiguous statutory requirements, where no regulations further define those requirements, cannot hold a defendant to the government's strict interpretation, so long as defendant's interpretation was reasonable." *Luckey*, 2 F. Supp. 2d at 1049.

[9] *See also United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 682, 684 (5th Cir. 2003) (en banc) (Jones J., concurring) ("Further, where disputed legal issues arise from vague provisions or regulations, a contractor's decision to take advantage of a position can not result in his filing a 'knowing' false claim. . . . Where there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim.") (citations omitted).

statement alleged to be false is ambiguous, the government (or here, the relator) must establish the defendant's knowledge of the falsity of the statement." *Id.* at 1053; *see also United States v. Estate of Rogers*, No. 1:97CV461, 2001 WL 818160, at *4 (E.D. Tenn. June 28, 2001) ("[I]t is immaterial whether the defendants did or did not make reasonable interpretations of the applicable HCFA rules and regulations . . . [T]he defendant's contention that they made a reasonable interpretation of HCFA's related-parties rules and regulations only goes to the scienter element and whether the defendants acted 'knowingly.'").

The Federal Circuit has gone off in yet another direction. In *Commercial Contractors v. United States*, 154 F.3d 1357, 1366 (Fed. Cir. 1998), it developed a more elaborate test based on the "plausibility" of the defendant's regulatory or contract interpretation and its state of mind.

> If a contractor submits a claim based on a plausible but erroneous contract interpretation, the contractor will not be liable, absent some specific evidence of knowledge that the claim is false or of intent to deceive. Yet when a contractor adopts a contract interpretation that is implausible in light of the unambiguous terms of the contract and other evidence (such as repeated warnings from a subcontractor or the fact that the interpretation is contrary to well-established industry practice), the contractor may be liable under the FCA or the CDA even in the absence of any deliberate concealment or misstatement of facts.

154 F.3d at 1366. The Federal Circuit offered this test without citation or any discussion of its underlying logical or precedential support.

As the cases referenced above demonstrate, the circuit courts often reach conflicting outcomes where confronted with FCA allegations based on ambiguous regulations or contract provisions. The practical implications of the divergent lower court analytical approaches to this issue cannot be overemphasized. A trial court is generally in a position early on in a case to determine whether the regulation or contract provision allegedly violated was ambiguous and whether the defendant's interpretation was reasonable as a matter of law. Consequently, defendants in some jurisdictions are able to win dismissal of the FCA action at an early stage. However, in those courts which consider ambiguity in the regulations or contracts allegedly violated to be immaterial or only relevant to the defendant's state of mind, defendants face expensive discovery and will encounter difficulty prevailing on motions prior to trial.[10] Faced with

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[10] *See United States v. Taber Extrusions, LP*, 341 F.3d 843, 846 (8th Cir. 2003) (in FCA case, "[p]articularly when the issue turns on the defendant's intent or scienter, summary judgment for the plaintiff is inappropriate"); *United States ex rel. Local 342 Plumbers & Steamfitters v. Dan Caputo Co.*, 321 F.3d 926, 931-32 (9th Cir. 2003) (in FCA case, "the extent to which contractors may be deemed to have knowledge . . . [is] both difficult and insufficiently developed on the current record to allow for summary judgment"); *see also Ashman v. Barrows*, 438 F.3d 781, 784 (7th Cir 2006) (noting that the court is "particularly leery of resolving issues involving a state of mind on summary judgment. . . [S]ummary judgment is notoriously inappropriate for determination of claims in which issues of intent, good faith and other subjective feelings play dominant roles.") (internal citation and quotation marks omitted); *Justofin v. Metropolitan Life Ins. Co.*, 372 F.3d 517, 524 (3d Cir. 2004) ("The issue of intent is particularly inappropriate for resolution by summary judgment") (internal quotation marks omitted); *Gelb v. Bd. of Elections*, 224 F.3d 149, 157 (2d Cir. 2000) ("summary judgment is generally inappropriate where questions of intent and state of mind are implicated").

such a prospect as well as the jury risk of potential treble damages and penalties, most FCA defendants will settle.

A stark example is provided by *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539 (E.D. Va. 2003). There, the district court agreed that the regulation at the core of the FCA allegations was ambiguous. According to the district court, the regulatory language allegedly violated by defendant's submissions to the Navy "ha[d] been the subject of considerable debate since the mid-1970's. Significantly, this debate unfolded not only between the government and industry, but among different government agencies, as well." *Id.* at 562. The court cited to several GAO reports, a federal district court opinion, and numerous articles and commentaries reflecting that "the debate regarding the proper interpretation of the regulatory phrase . . . has been an ongoing and unresolved question since that time [the mid-1970's]." *Id.* at 562-63. Yet, despite the undisputed and longstanding ambiguity in the regulation allegedly violated, the district court declined to grant summary judgment for defendant Newport News Shipbuilding. Instead, the trial judge found that there were still material factual issues relating to the defendant's knowledge under the FCA.[11] Within weeks of the denial of its summary judgment motion, the defendant agreed to pay approximately $60 million in a

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[11] The FCA's knowledge standard requires that a plaintiff demonstrate (i) actual knowledge of the falsity, (ii) deliberate ignorance of the falsity; or (iii) reckless disregard of the falsity. 31 U.S.C. § 3729(b). Although recognizing that the regulation was ambiguous and long debated, the district court refused to grant summary judgment because it ruled that there were issues under a reckless disregard theory. According to the *Newport News* court, a fact-finder "might conclude that NNS acted with reckless disregard as to the impermissibility under the FAR [Federal Acquisition Regulations] of its Double Eagle IR&D charges." 276 F. Supp. 2d at 566.

settlement. *See* Peter Pae, *Northrop Settles Two U.S. Suits*, L.A. TIMES, Aug. 27, 2003, § 3, at 2.

The FCA was intended to address contractors defrauding the United States.[12] Yet, *Newport News* and other similar cases allow FCA actions to proceed based on "disputed legal issues" of interpretation of ambiguous regulations and contracts. FCA cases arising from reasonable interpretations of ambiguous regulations and contracts should not be permitted to waste judicial and party resources, nor should they be used to extract multi-million dollar settlements from defendants. Only the Supreme Court can end the confusion and impose uniformity on this important issue. This Court should grant the petition and prevent FCA cases from going forward where the defendant has submitted a claim for reimbursement relying on a reasonable interpretation of an ambiguous regulation or contract.

B. The Eleventh Circuit's Decision Conflicts With Numerous Criminal False Claims Act Cases

Supreme Court review is especially appropriate here because the Eleventh Circuit decision – as well as the other lower courts that have allowed similar FCA actions to go forward based on alleged violations of ambiguous regulations and contracts – conflicts with a long line of decisions interpreting the parallel criminal FCA statute, 18 U.S.C. § 287.

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[12] The United States has a vast array of administrative and judicial remedies available to it to address contractual disputes with its contractors. Through these avenues, the government may be entitled to recover under contractual or common law theories from a contractor who adopts a reasonable interpretation contrary to the government's view of an ambiguous regulation or contract. However, the contractor should not be accused of defrauding the United States under the FCA nor subject to the FCA's treble damages and penalties.

Historically, the criminal and civil FCA was a single statute, with two penalties. Act of March 2, 1863, ch. 67, 12 Stat. 696-98. The original 1863 Act created one standard of liability for individuals who "present or cause to be presented . . . any claim upon or against . . . the United States . . . knowing such claim to be false, fictitious, or fraudulent." The Act provided that violators were subject to both a criminal and civil penalty—imprisonment for "not less than one nor more than five years" (criminal) and fines of $2,000 per act of fraud as well as "double the amount of damages which the United States may have sustained" (civil). *Id.*

In 1874, the criminal and civil provisions of the FCA were re-codified separately,[13] but the language regarding liability was fundamentally unchanged. *See Olson v. Mellon*, 4 F. Supp. 947, 949 (W.D. Penn. 1933), *aff'd sub nom. United States ex rel. Knight v. Mellon*, 71 F.2d 1021 (3rd Cir. 1934).[14] In *Olson v. Mellon*, the relator conceded that the criminal FCA did not reach to income tax fraud; nevertheless, the relator claimed that the civil FCA should be given a more "liberal construction" and therefore should impose liability on persons who commit income tax fraud. 4 F. Supp. at 949. The Third Circuit affirmed the dismissal of plaintiff's action, maintaining a single standard of liability for criminal and civil actions brought under the FCA.

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[13] The criminal and civil sections of the FCA have undergone numerous reenactments and re-codifications. Currently, the portions of the Act imposing criminal penalties are codified in 18 U.S.C. §§ 286, 287, 1001, and 1002. The portions of the act providing for civil remedies are codified 31 U.S.C. §§ 3729 – 3733. The text of these provisions is set out in the Appendix at pages 38a-59a.

[14] Liability under the two sections remained so similar that particularly ambitious citizens waited for the United States to file criminal indictments under the FCA and then filed their own civil FCA suits as relators. *See* S. REP. No. 345, 99th Cong., 2d Sess. at 10-12, *reprinted in* 1986 U.S.C.C.A.N. 5266, 5275-76.

In 1943, the Supreme Court confirmed this 'one standard of liability with two penalties' view. In *United States ex rel. Marcus v. Hess*, 317 U.S. 537 (1943), the Court held that the substantive language in both the civil and criminal FCA must have the same meaning for purposes of judicial construction. The Supreme Court rejected the defendant's contention that the civil and criminal FCA statutes should be construed differently.

> [W]e cannot say that the same substantive language has one meaning if criminal prosecutions are brought by public officials and quite a different meaning where the same language is invoked by an informer.

Id. at 542. The *Hess* Court found that the criminal and civil sections of the FCA were part of a single substantive scheme providing "both for a criminal punishment and a civil remedy" and ruled that the defendant was subject to liability in both arenas. *Id.* at 549. *Cf. Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) (applying "the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.") (internal quotation marks omitted).

Although subsequently amended, the substantive provisions of the criminal and civil FCA did not change and should continue to be construed in the same manner. Thus, a jury verdict or plea in a criminal FCA case remains res judicata in a civil FCA case. 31 U.S.C. § 3731(d).[15] In

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[15] *See, e.g., United States v. Szilvagyi*, 398 F. Supp. 2d 842, 844-45 (E.D. Mich. 2005); *United States v. St. Luke's Subacute Hosp.*, No. 00-1976, 2004 WL 2905237, at *4 (N.D. Cal. Dec. 16, 2004); *United States v. Cripps*, 460 F. Supp. 969, 976-77 (E.D. Mich. 1978).

addition, courts interpreting the language of the civil FCA continue to look and cite to the criminal FCA for guidance.[16] The two statutes continue to share similar language regarding the key substantive elements.[17] Given the Supreme Court's directive in *Marcus v. Hess* regarding the treatment of similar substantive language in both statutes, and given the lack of any changes to the key substantive elements, the criminal and civil FCA should continue to be construed in a consistent fashion.

Yet, contrary to their historical development and Supreme Court guidance, the criminal and civil FCA statutes have been construed very differently concerning alleged violations of ambiguous regulations or contracts. Unlike the

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[16] *See e.g.*, *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) (citing criminal FCA case, *United States v. Burns*, 162 F.3d 840 (5th Cir. 1998), to support the proposition that the defendant must know the claim was "false or fraudulent"); *UMC Elecs. Co. v. United States*, 43 Fed. Cl. 776, 794 (1999) (citing to a criminal FCA case, *United States v. Race*, 632 F.2d 1114 (4th Cir. 1980), in discussing the use of expert testimony to determine "falsity"); *United States v. Hughes Helicopter Co.*, No. CV 89-5760SVN, 1993 WL 841192 (C.D. Cal. Aug. 25, 1993) (citing to *Race*, 632 F.2d 1114, to support its holding that the government failed to prove that the defendant's claims were "false"), *aff'd*, 71 F.3d 321 (9th Cir. 1995).

[17] The civil portion of the Act imposes liability on any person who "knowingly presents, or causes to be presented to an officer or employee of the United States government . . . a false or fraudulent claim for payment or approval" or any person who "knowingly makes . . . a false record or statement to get a false or fraudulent claim paid or approved by the Government." 31 U.S.C. § 3729(a). The criminal portion of the Act imposes a fine and up to five years in prison for "[w]hoever makes or presents to any person or officer . . . of the United States . . . any claim upon the United States, or any department or agency thereof, knowing such claim to be false, fictitious or fraudulent . . . ." 18 U.S.C. § 287. While post-1986 the plaintiff must prove that the claim was false by a "preponderance of the evidence" in the civil context, the 1986 Amendments did not alter the substantive definition of falsity. 31 U.S.C. § 3731(c).

decision below and many other civil FCA decisions, the circuit courts in the criminal context have been unwilling to allow prosecutions to go forward where the alleged FCA violation is based on a reasonable interpretation of an ambiguous regulation or contract. The criminal FCA cases have set a considerably more stringent standard. Numerous circuit courts have held that no liability exists where the defendant in a criminal FCA case relied on a reasonable interpretation of the regulation or contract provision. As the Tenth Circuit has stated, "the Government bears the burden to negate any reasonable interpretations that would make a defendant's statement factually correct where reporting requirements are ambiguous." *United States v. Migliaccio*, 34 F.3d 1517, 1525 (10th Cir. 1994).[18] *See, e.g., United States v. Whiteside*, 285 F.3d 1345, 1351-52 (11th Cir. 2002) ("In a case where the truth or falsity of the statement centers on an interpretative question of law, the government bears the burden of proving . . . that the defendant's statement is not true under a reasonable interpretation of the law."); *United States v. Johnson*, 937 F.2d 392, 399 (8th Cir. 1991) ("The Government must negative any reasonable interpretation that would make the defendant's statement factually correct.") (internal quotation marks omitted); *United States v. Race*, 632 F.2d 1114, 1120 (4th Cir. 1980) (defendant "cannot be found guilty of a false statement under a contract beyond a reasonable doubt when his statement is within a reasonable construction of the contract."); *United States v. Anderson*, 579 F.2d 455, 460 (8th Cir. 1978) ("In light of these ambiguities, . . . the government must negative any reasonable interpretation

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[18] The criminal laws alleging fraud against the United States are prosecuted as false statements and/or false claims violations under 18 U.S.C. §§ 287, 1001. The same statutory construction should apply to these two statutes as to the FCA. Section 3729(a)(2) of the civil FCA, for example, makes it a violation to "knowingly make[] . . . a *false record or statement* to get a" false claim paid by the Government. *See supra* at n.16.

that would make the defendant's statement factually correct.").[19]

The Eleventh Circuit held the case against R&F could go forward since the plaintiff could show that she had a reasonable regulatory interpretation. In contrast, the numerous criminal cases involving defrauding the government hold that no liability attaches if the defendant's interpretation of the regulation or contract is reasonable. The Supreme Court should grant certiorari to resolve this conflict and ensure that "the same substantive language has one meaning" in criminal and civil FCA proceedings.

II. THE DECISION BELOW VIOLATES BASIC CONSTITUTIONAL AND COMMON LAW PRINCIPLES

This Court has recognized that the civil FCA is "essentially punitive in nature." *Vermont Agency of Natural Res. v. United States ex rel. Stevens,* 529 U.S. 765, 784 (2000). The 1986 Amendments to the civil FCA imposed treble damages and penalties of $5,500 to $11,000 (now adjusted for inflation) per false claim. These enhanced damages and penalties went beyond what was necessary to compensate the United States for any losses. The Court noted that "the very idea of treble damages reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers." *Id.* at 786 (quoting *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 639 (1981)). In 2003, although acknowledging that the treble

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[19] *See also United States v. Barsanti,* 943 F.2d 428, 432 (4th Cir. 1991) (adopting *Anderson* and *Race* in requiring that government has burden of "negativ[ing] any reasonable interpretation that would make the defendant's statement factually correct"); *United States v. Dale*, 991 F.2d 819, 833 (D.C. Cir. 1993) (same).

damages had a compensatory side, the Supreme Court reaffirmed its characterization of the post-1986 FCA as an "essentially punitive" statute. *Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 120 (2003).[20]

In light of the punitive sanctions facing FCA defendants, the Eleventh Circuit's decision does not comport with basic constitutional and common law protections. First, the Eleventh Circuit's decision violates the fair notice requirement of due process by holding a government contractor liable even if it is unaware of the falsity of its claim due to the regulation's ambiguity. Second, the Eleventh Circuit's decision violates the rule of lenity's requirement that ambiguities be resolved in a defendant's favor when penal sanctions are implicated. Finally, the Eleventh Circuit's decision violates the well-established doctrine of *contra proferentem* which requires construing ambiguous language against the drafter of the language, here the United States. While compensatory, contractual-based damages may be appropriate, this Court should grant review and declare that the FCA's extreme sanctions cannot be used to punish a reasonable interpretation of an ambiguous regulation or contract.

A. The Eleventh Circuit's Decision Is Contrary To The Due Process Clause

Due process requires that a person receive "fair warning" that his conduct is unlawful. *United States v.*

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[20] *See also United States v. Mackby*, 261 F.3d 821, 831 (9th Cir. 2001) (civil FCA penalties are "not solely remedial . . . [they are] subject to an Excessive Fines Clause analysis under the Eighth Amendment"); *United States ex rel Dunleavy v. County of Delaware*, 279 F.3d 219, 223 (3rd Cir. 2002) ("the FCA's treble damages provision is punitive"), *vacated on other grounds*, 538 U.S. 918 (2003); *Hays v. Hoffman*, 325 F.3d 982, 992 (8th Cir. 2003) ("we agree with the Ninth Circuit that FCA penalties are punitive in nature").

Lanier, 520 U.S. 259, 265 (1997) ("The . . . principle is that no man shall be held criminally responsible for conduct which he could not reasonably understand to be proscribed.") (internal quotation marks omitted). An essential component of fair notice is the requirement that a statute or regulation be written with sufficient clarity and not be so ambiguous that "men of common intelligence must necessarily guess at its meaning and differ as to its application." *Id.* at 266 (internal quotation marks omitted); *see also Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972) ("It is a basic principle of due process that an enactment is void for vagueness if its prohibitions are not clearly defined.").

While most commonly found in the criminal context, courts also apply a fair notice requirement for deprivation of property in the civil context. *See Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 314 (1950). The Due Process Clause thus has been found to prevent the imposition of administrative sanctions without adequate warning of the conduct prohibited. *See, e.g.*, *United States v. Hoechst Celanese Corp.*, 128 F.3d 216, 217 (4th Cir. 1997) ("A regulation which allows monetary penalties against those who violate it must give fair warning of the conduct it prohibits or requires, and it must provide a reasonably clear standard of culpability.") (citations and quotations omitted); *General Elec. Co. v. EPA*, 53 F.3d 1324, 1328-29 (D.C. Cir. 1995) ("In the absence of notice — for example, where the regulation is not sufficiently clear to warn a party about what is expected of it — an agency may not deprive a party of property by imposing civil or criminal liability."); *Satellite Broad. Co. v. FCC*, 824 F.2d 1, 4 (D.C. Cir. 1987) ("The Commission through its regulatory power cannot, in effect, punish a member of the regulated class for reasonably interpreting Commission rules.").

The application of due process principles to ambiguous agency pronouncements can be seen most clearly

in a case involving penalties assessed a defendant under OSHA regulations. *See Gates & Fox Co. v. OSHRC*, 790 F.2d 154, 156 (D.C. Cir. 1986). Then Judge Scalia, writing for the court, stated that "[i]f a violation of a regulation subjects private parties to criminal or civil sanctions, a regulation cannot be construed to mean what an agency intended but did not adequately express . . . . [T]he Secretary as enforcer of the Act has the responsibility to state with ascertainable certainty what is meant by the standards he has promulgated." *Id.* at 156. Finding the regulation ambiguous and the defendant's interpretation of the statute reasonable, the D.C. Circuit held that the regulation failed to give fair notice sufficient to impose penalties. *Id.* at 156-57.[21]

If a government contractor cannot discern the meaning of the regulation and follows a reasonable interpretation of the requirements, it cannot be held liable for punitive sanctions. *See General Elec.*, 53 F.3d at 1329; *see also Trinity Broad. of Fla., Inc. v. FEC*, 211 F.3d 618, 628 (D.C. Cir. 2000). Here, there is no dispute that the regulation relating to billing nurse practitioners was ambiguous. The *qui tam* relator was unable to point to any binding agency promulgations that provided sufficient warning. Tellingly, the Government elected not to intervene in this FCA lawsuit. Moreover, the regulation had to be amended in 2002 to clarify its meaning on this very point relating to the meaning of the "incident to the service of a physician" language. *See* 42

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[21] *See also United States v. Hoechst Celanese Corp.*, 128 F.3d 216 (4th Cir.1997) (finding agency interpretation of regulations to be permissible but setting aside administrative sanctions on fair warning grounds because of ambiguity in the regulations); *General Elec. v. EPA*, 53 F.3d 1324, 1333-34 (DC Cir. 1995) (same; "Where, as here, the regulations and other policy statements are unclear, where the petitioner's interpretation is reasonable, . . . EPA thus may not hold GE responsible" for agency punishment), *Rollins Environmental Services, Inc. v. EPA*, 937 F.2d 649 (D.C. Cir. 1991) (same). Envtl. Servs.

C.F.R. § 410.26 (2002). In these circumstances, it is evident that R&F's interpretation was reasonable in the face of the regulation's then-existing ambiguity and that the fair warning necessary to impose the FCA's penal sanctions is wholly lacking.

For due process purposes, a person should not be subject to punishment for a false claim if the regulation under which the claim is made is ambiguous and the claimant's interpretation of the regulation is reasonable. This petition should be granted so that this Court can reaffirm this elemental principle.

B. The Eleventh Circuit's Decision Is Contrary To The Rule of Lenity

The rule of lenity is "the canon of strict construction of criminal statutes [which] ensures fair warning by so resolving ambiguity in a criminal statute as to apply it only to conduct clearly covered." *United States v. Lanier*, 520 U.S. 259, 266 (1997). In operation, it is an interpretive rule which states that when a criminal statute is ambiguous, courts will resolve the ambiguity in favor of the accused. *United States v. Kozminiski*, 487 U.S. 931, 952 (1988); *see also Whalen v. United States*, 445 U.S. 684, 694-95 & n.10 (1980).

The rule of lenity has been extended outside of the purely criminal context. In *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 517 (1992), a firearms manufacturer sued for a refund of tax imposed under the National Firearms Act ("NFA"). The Supreme Court concluded that the NFA was ambiguous in its definition of firearms subject to a special excise tax under that statute. Although a civil tax case, the Supreme Court applied the rule of lenity and resolved the ambiguity in the taxpayer's favor. *Id.* In doing so, the Court noted that the NFA had both civil and criminal applications and therefore found it appropriate to apply the

rule of lenity in light of the duel nature of many aspects of the NFA. The *Thompson* Court explicitly rejected the argument that "lenity should not be applied because this is a 'tax statute' rather than a 'criminal statute.'" *Id.* at n.10 (citing *Crandon v. United States,* 494 U.S. 152, 168 (1990) (applying rule of lenity to a civil complaint which invoked criminal conflict of interest provisions)).

As discussed above, the civil FCA is similarly intertwined with its criminal counterpart. Thus, the *Thompson* Court's reasoning that lenity is appropriate even if a statute is construed in its civil setting, rather than in its criminal setting, applies with equal force to the treatment of ambiguous regulations in the FCA context. The rule of lenity demands that the ambiguity in the regulations or contracts be construed in favor of the defendant. This rule of construction argues against imposing punitive FCA treble damages and penalties on claims for reimbursement submitted based on R&F's reasonable interpretation of an admittedly ambiguous regulation. The rule of lenity has several underlying policy rationales: to promote fair notice to those subject to penal sanctions, to minimize the risk of selective or arbitrary enforcement, and to maintain the proper balance between Congress, prosecutors and courts. *Kozminiski,* 487 U.S. at 952; *United States v. Bass*, 404 U.S. 336, 347-348 (1971). These policy rationales are all advanced by declining to base FCA punishments on reasonable interpretations of ambiguous regulations or contracts.

C. Eleventh Circuit's Decision Is Contrary To The Principle Of Interpreting An Ambiguous Provision Against Its Drafter

The doctrine of *contra proferentem* is a "general maxim that a contract should be construed most strongly against the drafter." *See United States v. Seckinger*, 397 U.S.

203, 210 (1970). Because the HCFA-1500 certification form and the relevant regulation, 42 C.F.R. § 410.26, incorporated into the Medicare reimbursement claims were drafted by the government, their ambiguity should be construed in favor of the defendant R&F and the government should not be allowed to gain the windfall of the FCA's treble damages and penalties.

"Contra proferentem applies when a contractor's reading of an ambiguous contract provision is reasonable in itself." *United States v. Turner Constr. Co.*, 819 F.2d 283, 286 (Fed. Cir. 1987). If the government concedes that that the language is ambiguous and that "there is an alternative construction of the clause that is both 'reasonable and practical,'" the "construction-against-drafter principle [will] operate." *Seckinger*, 397 U.S. at 211. Interpretation of ambiguous contract terms against the drafter is favored when the government dictated the provisions of the contract. *Id.* at 216.

Here, R&F has a contractual relationship with the government under the Medicare program. *See* 42 C.F.R. § 489.11 (2005) ("If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS . . . ."); *see also* 42 CFR §§ 489.1–489.10; 489.12–489.18 (2005). The HCFA form and regulation are part of the contractual relationship whereby R&F is reimbursed for its treatment of patients pursuant to this contractual agreement. R&F has engaged in a reasonable interpretation of an ambiguous provision drafted by the government. Accordingly, the doctrine of contra proferentem compels that the ambiguity be construed in favor of R&F and no FCA liability attach to its reimbursement claim submitted under this government contract.[22]

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[22] In *Turner*, the Federal Circuit construed a contract against the United States as drafter:

III. THE QUESTION PRESENTED IN THIS CASE IS FAR-REACHING AND OF EXCEPTIONAL IMPORTANCE

The issue presented by this petition – whether contractors can be subject to FCA lawsuits based on reasonable interpretations of ambiguous regulations or contracts – is of great consequence for all entities contracting with the United States government. The United States government is the world's largest consumer of goods and services, with total discretionary spending under FY 2007 expected to exceed $870.7 billion. Virtually every major American business provides some product or service to the federal government. Subjecting the many companies that contract with the federal government to the treble damages and penalties of the FCA in instances where they reasonably interpret ambiguous regulations or contracts will result in the federal government incurring higher costs and may even deter some companies from contracting with the government.[23]

> Having concluded that Turner's interpretation of the contract was reasonable, we apply the rule of *contra proferentem*, which requires that a contract be construed against the party who drafted the document. *Contra proferentem* applies when a contractor's reading of an ambiguous contract provision is reasonable in itself. This rule correctly requires the drafter to use care and completeness in creation of a contract.

819 F.2d at 286 (internal citations omitted).

[23] According to a report issued by the American Medical Association, 52% of physicians reported that the complexity of the regulations made them less inclined to see Medicare patients. AMERICAN MEDICAL ASSOCIATION, *Rethinking Medicare: Solutions for Medicare's Short- and Long-term Problems* (2002), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/363/rethinkingmedicare.pdf.

Goods and services are invariably provided to the government pursuant to a web of complex government regulations or contracts. The Medicare regulations have been called by courts "among the most completely impenetrable texts within human experience." *Rehab. Ass'n v. Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994). The FDA laws governing pharmaceuticals are equally problematic.[24] Defense contractors are subject to the multi-volume Federal Acquisition Regulations.[25] The rules governing leasing of energy resources also are exceedingly dense and complicated.[26]

These complex regulations and contracts are, in effect, a trap for the unwary. Under the Eleventh Circuit's decision and other similar lower court decisions, the ambiguity in these regulations and contracts can be turned against the private contractor so that a private plaintiff or the Department of

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[24] *See, e.g., Washington Legal Foundation v. Henney*, 128 F. Supp. 2d 11 (D.D.C. 2000) ("[a]fter six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct" under FDAMA and CME guidelines).

[25] *See, e.g. United States v. Data Translation, Inc.*, 984 F.2d 1256, 1261 (1st Cir. 1992) (Breyer, J.) (affirming dismissal of FCA action; "we think a literal reading of the [government] disclosure form creates ambiguity and incomprehensibility and . . . we conclude that no reasonable person . . . could have believed that the Government really wanted [what] the language seems to ask."); *X Corp. v. Doe*, 816 F. Supp. 1086 (E.D. Va. 1993) (applicable FAR regulations so complex that no one understood them).

[26] *See, e.g., United States ex rel. Grynberg v. Praxair, Inc.*, 207 F. Supp. 2d 1163 (D. Colo. 2001) (discussing complex agreement between government and defendant regarding methodology for measuring and reporting gas production and gas volumes for royalty purposes), *rev'd in part on other grounds*, 389 F.3d 1038 (10th Cir. 2004).

Justice can extract large FCA settlements. The reality is that few businesses want to incur the risk, expense, distraction and negative press involved in going to trial, especially when faced with the possibility of treble damages and penalties of $11,000 per claim. However, the Eleventh Circuit's decision below, as well as other similar lower court decisions, prevent early dismissal of these FCA cases grounded on ambiguous regulations and contracts. Instead, these FCA cases based on reasonable interpretations of ambiguous regulations or contracts are allowed to proceed forward.

The result is FCA defendants often being forced to enter into extremely large settlements.[27] At a minimum, businesses must incur significantly greater legal fees to take these FCA cases through to summary judgment and even trial in order to eventually prevail. This is unfair and legally wrong where the alleged violation is a failure to comply with an ambiguous regulation or contractual provision. This Court should grant the petition and resolve the confusion among the lower courts by holding that a reasonable interpretation of an ambiguous regulation or contract cannot form the basis of a FCA violation.

CONCLUSION

The petition for a writ of certiorari should be granted.

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[27] Within the last several months, Tenet agreed to a $900 million FCA settlement with the United States, and Saint Barnabas Health Care System paid $265 million to resolve FCA allegations. Daniel Yi, *Tenet to Pay $900 Million to Settle U.S. Allegations*, L.A. TIMES, Jun. 30, 2006, at C1.

Respectfully submitted.

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July 2006

Supreme Court, U.S.
FILED
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OFFICE OF THE CLERK

No.

IN THE
Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,
F/K/A LEESBURG FAMILY MEDICINE,
Petitioner,

v.

UNITED STATES OF AMERICA *EX. REL* KARYN L. WALKER,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

APPENDIX TO THE PETITION FOR A WRIT OF CERTIORARI

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TABLE OF CONTENTS

Page

Appendix A (court of appeals opinion, filed Dec. 30, 2005) 1a

Appendix B (district court order, filed Oct. 6, 2004) 20a

Appendix C (court of appeals order denying rehearing and rehearing en banc, filed Mar. 31, 2006) 37a

Appendix D (Constitutional, statutory, and regulatory provisions) 38a

Appendix A

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-15283

D.C. Docket No. 02-00131-CV-OC-10-GRJ

UNITED STATES, ex rel.,

Plaintiff,

KARYN L. WALKER,
a.k.a. Karyn L. Denk-Walker,

Plaintiff-Appellant
Cross-appellee

versus

R & F PROPERTIES OF LAKE COUNTY, INC.,
A Florida Professional Association,

Defendant-Appellee
Cross-Appellant.

Appeals from the United States District Court
for the Middle District of Florida

(December 30, 2005)

Before BIRCH, WILSON and COX, Circuit Judges.

COX, Circuit Judge:

Plaintiff Karyn L. Walker is a *qui tam* relator, seeking recovery on behalf of the United States pursuant to the False Claims Act, 31 U.S.C. § 3729. Walker appeals a summary judgment granted to Defendant R&F Properties of Lake County, Inc., formerly known as Leesburg Family Medicine, (LFM). And Walker contends that the district court erred in limiting the scope of information discoverable in the case to that information relevant to the time period during which she was employed by LFM as a nurse practitioner. LFM cross-appeals, contending that the district court erred in denying its motion to dismiss Walker's Amended Complaint.

We conclude that the district court erred in holding that Walker had not produced sufficient evidence of the falsity of the claims submitted by LFM to resist summary judgment. Therefore, we reverse the district court's judgment. We also find error in the district court's order limiting discovery. We find no error in the district court's denial of LFM's motion to dismiss.

I. BACKGROUND & PROCEDURAL HISTORY

The Medicare Program is a system of health insurance administered by the United States Department of Health and Human Services, through the Center for Medicare and Medicaid Services (CMS). CMS was formerly known as the Health Care Financing Administration (HCFA). Medicare Part B is a federally subsidized, voluntary health insurance program that pays a portion of the costs of certain health services, including the costs of clinic visits to healthcare providers (among them, physicians, physician assistants, and nurse practitioners). Reimbursement for Medicare Part B claims is made through CMS, which contracts with private insurance carriers throughout the United States to administer and pay claims within their regions from the Medicare Trust Fund. These insurance carriers are known as Fiscal Intermediaries, or FIs. In general, when a healthcare service

is rendered to a patient covered by Medicare Part B, the healthcare provider bills Medicare/CMS through the FI. The FI reviews the bill and pays the healthcare provider. CMS publishes a series of manuals that provide billing and payment instructions to the Medicare community. Among these manuals are the Medicare Carrier's Manual, directed to the FIs, and the Provider Reimbursement Manual, directed to healthcare providers.

LFM operates medical clinics in Leesburg and Lady Lake, Florida. At these clinics, physicians, physician assistants, and nurse practitioners provide medical services to the community. Many, if not most, of LFM's patients are covered by Medicare Part B. LFM submits claims for Medicare reimbursement for healthcare services rendered by physicians, physician assistants and nurse practitioners to its FI, Blue Cross Blue Shield of Florida, pursuant to a contract between LFM and Blue Cross Blue Shield. These claims are made on HCFA 1500 forms in electronic form, as required by the Medicare regulations, and signed electronically by LFM's physicians. Each HCFA 1500 form states:

> SIGNATURE OF PHYSICIAN OR SUPPLIER
> (MEDICARE, CHAMPUS, FECA AND
> BLACK LUNG)
>
> I certify that the services shown on this form were medically indicated and necessary for the health of the patient and were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision, except as otherwise expressly permitted by Medicare or CHAMPUS regulations.
>
> For services to be considered "incident" to a physician's professional service, 1) they must be rendered under the physician's immediate personal

> supervision by his/her employee, 2) they must be an integral, although incidental part of a covered physician's service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of nonphysicians must be included on the physician's bills.

(R.2-79 Ex. G.)

Healthcare providers may bill Medicare Part B for the services of physician assistants and nurse practitioners in one of two ways; the amount of reimbursement the providers receive is dependent on the billing method. Physician assistant or nurse practitioner services may be billed as services "incident to the service of a physician." 42 CFR §§ 410.10, 410.26. To be correctly billed in this manner, the physician assistant or nurse practitioner services must have been provided under certain circumstances.[1] When physician assistant or nurse practitioner services are billed as "incident

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[1] For the relevant time period prior to January 1, 2002, 42 CFR § 410.26 stated:

> (a) Medicare Part B pays for services and supplies incident to a physician's professional services, including drugs and biologicals that cannot be self-administered, if the services or supplies are of the type that are commonly furnished in a physician's office or clinic, and are commonly furnished either without charge, or included in the physician's bill.

Effective January 1, 2002, 42 CFR § 410.26 was amended to read, in relevant part:

> (b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).
>
> (1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

to the service of a physician," the physician's Unique Provider Identification Number (UPIN) is used on the bill submitted to the FI. Alternatively, a provider may bill Medicare for physician assistant and nurse practitioner services under the physician assistant's or nurse practitioner's own UPIN. Billing Medicare in this second way indicates that the physician assistant or nurse practitioner has performed the service under some level of supervision by a physician, but the requirements of 42 CFR § 410.26 have not necessarily been met. For services billed under a physician assistant's or

---

> (2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.
>
> (3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).
>
> (4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).
>
> (5) Services and supplies must be furnished under the direct supervision of the physician (or other practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

. . .

"Direct supervision," as used in 42 CFR § 410.26, is defined by reference to 42 CFR § 410.32(b)(3)(ii), a provision that, since 1998, states:

> *Direct supervision* in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed.

nurse practitioner's UPIN, the FI pays 85% of what it would pay for the same services billed under a physician's UPIN.

Walker worked for LFM from February 1997 until May 1999 as a nurse practitioner. During that time, there were many occasions when she saw patients independently without physician supervision. Physicians were not always physically present in the LFM clinic while Walker and other nurse practitioners and physician assistants saw patients, but physicians were always available for consultation by pager and telephone.

II. CONTENTIONS OF THE PARTIES

Walker brings this suit as a *qui tam* relator under the False Claims Act. She alleges that LFM filed false claims for Medicare reimbursement by billing Medicare for services rendered by nurse practitioners and physician assistants as if those services were rendered "incident to the service of a physician," even though LFM knew that the nurse practitioner and physician assistant services did not meet several of the criteria necessary for billing in that manner. Chief among Walker's complaints is that LFM billed all nurse practitioner and physician assistant services as "incident to the service of a physician," even though the nurse practitioners and physician assistants often treated patients at LFM's clinics when no physician was physically present in the clinic. She contends that a physician's physical presence within the office suite was required in order for the nurse practitioner's or physician assistant's service to have been rendered "incident to the service of a physician," as used in 42 CFR § 410.26 and "under the physician's immediate personal supervision" as certified by the physician on each HCFA 1500 claim form. Walker further contends that LFM knew that its billing practice was fraudulent and that LFM knew the proper way to bill the services (as services rendered directly by the nurse practitioner or physician assistant rather than as services

"incident to the service of a physician"). Walker alleges that, as a result of the fraudulent manner in which LFM billed Medicare, LFM was paid 15% more than it should have been paid for nurse practitioner and physician assistant services to Medicare patients.

LFM admits that physicians were not always physically present in the clinic while nurse practitioners and physician assistants treated patients. LFM also admits that it submitted HCFA 1500 forms to Blue Cross Blue Shield requesting Medicare reimbursement for services of nurse practitioners and physician assistants performed "incident to the service of a physician," even if the nurse practitioner and physician assistant services were performed while no physician was physically present in the LFM office suite. LFM further concedes that the submission of the HCFA 1500 forms constitutes the presentation of claims for purposes of the False Claims Act. However, LFM argues that, as a matter of law, these claims could not have been false within the meaning of the False Claims Act because the phrase "incident to the service of a physician" was, at least until January 1, 2002, vague and subject to reasonable interpretations other than that championed by Walker. It further argues that the "immediate personal supervision" language in the HCFA 1500 certification is similarly vague and therefore, as a matter of law, cannot be the basis for a false claim.

The parties also disagree about the time period relevant to Walker's lawsuit. Walker maintains that LFM made false claims for physician assistant and nurse practitioner services performed from the time it first hired a physician assistant in 1994 through the date Walker filed her complaint, and she argues that her complaint properly alleges the existence of false claims throughout this entire period. LFM, on the other hand, contends that Walker could allege properly only that

false claims were presented from February 1997 through May 1999, the dates of her employment at LFM.[2]

The district court granted LFM summary judgment because it found that LFM's requests for reimbursement could not be false as a matter of law. The district court reasoned that, because the Medicare statutes and regulations in effect during the period of Walker's employment with LFM did not adequately define the phrase "incident to the service of a physician" and because the terms "immediate," "integral," and "incidental" as used on the HCFA 1500 form "are inherently imprecise," LFM's interpretation of the terms (that nurse practitioners and physician assistants could see patients independently so long as a physician was available by pager and telephone) must be accepted as reasonable. In opposition to LFM's motion for summary judgment, Walker offered evidence of how the regulatory language and the HCFA 1500 certification language were interpreted in the Medicare community. Walker contends that this evidence would support a finding that the claims submitted were false. However, the district court considered the evidence insufficient to present an issue of fact as to the meaning of the terms.

III. ISSUES ON APPEAL

To determine whether the district court erred in granting summary judgment, we must decide whether the Medicare regulations and HCFA 1500 form are unclear regarding the criteria that must be fulfilled in order for services of a nurse

---

[2] According to LFM, however, this is a hypothetical. LFM contends that Walker's Amended Complaint does not properly plead any cause of action regarding any time period and that it should have been dismissed by the district court because it is not specific enough to satisfy the pleading requirements of Federal Rule of Civil Procedure 9(b).

practitioner or physician assistant to be billed as services "incident to the service of a physician." If we decide that they are unclear, we must then decide whether a court may look to evidence other than the language of the regulation and form to determine whether a claim, allegedly submitted in violation of that language, is false within the meaning of the False Claims Act. If we decide that a court may look to evidence outside the language at issue, we must determine whether the evidence Walker presented in opposition to LFM's motion for summary judgment is sufficient to create an issue of fact as to the falsity of the claims LFM made to Medicare.

We also decide whether the district court erred in limiting discovery in the action to information relevant to the time period during which Walker was employed by LFM.

Finally, to decide LFM's cross-appeal, we determine whether Walker's Amended Complaint satisfies the requirements of Rule 9(b).

IV. STANDARDS OF REVIEW

We review the district court's grant of summary judgment de novo, applying the same legal standards that bound that court and "viewing all facts and reasonable inferences in the light most favorable to the nonmoving party." *Strickland v. Water Works and Sewer Bd. of the City of Birmingham*, 239 F.3d 1199, 1203 (11th Cir. 2001). Summary judgment is appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

The district court's discovery decisions are reviewed for abuse of discretion. *See Burger King Corp. v. Weaver*, 169 F.3d 1310, 1315 (11th Cir. 1999).

We review de novo the denial of a motion to dismiss. *See Nolen v. Jackson*, 102 F.3d 1187, 1190 (11th Cir. 1997).

V. DISCUSSION

The False Claims Act states:

> Any person who . . . knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .

31 U.S.C. § 3729(a). The False Claims Act authorizes private citizens to bring actions on behalf of the United States. 31 U.S.C. § 3730(b). These plaintiffs are known as *qui tam* relators. To establish a cause of action under the False Claims Act, a relator must prove three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false. 31 U.S.C. § 3729(a). Recovery under the False Claims Act is not measured by the amount of any actual damage a relator might have sustained personally as a result of a defendant's false claim. Rather, the relator stands in the shoes of the United States government. She can prosecute the lawsuit on the United States' behalf, and recover, for the United States, the losses attributable to any fraudulent claim and the civil penalty authorized by the statute. 31 U.S.C. § 3730.

A. The Grant of Summary Judgment

In this case, the district court granted summary judgment for LFM because it found that, as a matter of law, Walker's complaint and evidence did not present the possibility of a false or fraudulent claim. As stated above, the district court found that the regulatory language that Walker claimed was

violated when LFM submitted its claims was ambiguous and therefore could not, as a matter of law, serve as the predicate for a false claims action. We find error in the district court's reasoning.

First, we note that the district court granted LFM summary judgment on Walker's entire complaint even though a subset of the claims alleged by Walker were allegedly submitted after the Medicare regulation had been amended and clarified. *See supra* n.1. As of January 1, 2002 (four months before Walker filed her original complaint in this case), the regulation providing conditions for coverage of services rendered "incident to the service of a physician" was clear about the meaning of that phrase. As of that date, all services billed as "incident to the services of a physician" must have been rendered under a physician's "direct supervision." 42 CFR § 410.26(b)(5) (2002). In order to satisfy this "direct supervision" requirement, "the physician must [have been] present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure." 42 CFR § 410.26(a)(2) (2002), 410.32(b)(3)(ii) (2002). This regulatory language unambiguously requires that a physician be present in the office. Furthermore, this new regulatory language illuminates the meaning of the physician certification on the HCFA 1500 form that the billed services "were personally furnished by me or were furnished incident to my professional service by my employee under my immediate personal supervision," at least as of January 1, 2002.

Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed. *See United States v. Calhoon*, 97 F.3d 518, 524 (11th Cir. 1996); *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975). Given the clear definition of services rendered "incident to the service

of a physician" that became effective January 1, 2002, Walker should be permitted to present evidence to a fact-finder supporting her allegations that any Medicare claims LFM submitted from January 1, 2002 until the date of her complaint for services of nurse practitioners or physician assistants "incident to the service of a physician," were not, in fact, rendered in compliance with the applicable Medicare regulation and, therefore, were false. An issue of fact also exists as to whether LFM physician certifications on the HCFA 1500 forms submitted from January 1, 2002 until the date of Walker's complaint were false.

Additionally, the district court erred by holding that any ambiguity in the earlier version of 42 CFR § 410.26 and the HCFA 1500 certification necessarily forecloses, as a matter of law, the falsity of claims submitted by LFM prior to January 1, 2002. We agree that the regulatory language in effect until January 1, 2002 was ambiguous. But we disagree as to the legal significance of that ambiguity. In opposition to LFM's motion for summary judgment, Walker submitted provisions from the Medicare Carrier's Manual, Medicare bulletins, seminar programs, and expert testimony regarding proper billing "incident to the service of a physician," as used in 42 U.S.C. § 410.26. She also presented two notes written by LFM's employee that paraphrase a billing consultant's advice. All of these sources were offered to show the meaning of the language in the regulation and on the HCFA 1500 form and the reasonableness of LFM's claimed understanding of that language. At least some of these sources would support a finding that, in the Medicare community, the language was understood to mean that a physician had to be physically present in the office suite and otherwise more involved in a patient's course of care than the LFM physicians were. The district court considered this evidence irrelevant and held that, because none of it held the force of law, it could not be the basis for a false claim.

As the district court recognized, the Supreme Court has stated that agency interpretations contained in policy statements, manuals, and enforcement guidelines are not entitled to the force of law. *Christensen v. Harris County*, 529 U.S. 576, 587, 120 S. Ct. 1655, 1662 (2000). For that reason, we agree with the district court that evidence of a defendant's failure to comply with an administrative guideline does not necessarily establish that the defendant presented legally false claims–claims in violation of a statute or regulation–to the United States. But that is not the issue here. What is at issue is whether any evidence outside the language of a Medicare regulation (including guidance issued by the governmental agency charged with administering the regulatory scheme) can be consulted to understand the meaning of that regulation. We hold that it can.

The Supreme Court has held that agency interpretations are "entitled to respect . . . to the extent that those interpretations have the power to persuade." *Id.*, 120 S. Ct. at 1663 (citing *Skidmore v. Swift & Co.*, 323 U.S. 134, 140, 65 S. Ct. 161, 164 (1944)). Our precedent is consistent. Indeed, we have followed this rule in the context of Medicare false claims cases. In affirming a criminal false claims conviction, this court looked to a manual published by HCFA to determine the meaning of a Medicare regulation and establish the falsity of the defendant's claims for Medicare reimbursement. *See Calhoon*, 97 F.3d at 526 (consulting the Provider Reimbursement Manual to define the meaning of a phrase in the Medicare regulations). The fact that the Medicare Carrier's Manual was not issued to Defendants does not negate its probative value regarding the meaning of a Medicare regulation. *See United States v. Gold*, 743 F.2d 800, 816 (11th Cir. 1984) (affirming criminal conviction of eye doctor for Medicare fraud and approving admission of Medicare Carrier's Manual provisions as evidence of what types of claims were properly payable under Medicare).

In a case remarkably similar to this one, the Eighth Circuit recently held, "If a statement alleged to be false is ambiguous, the government (or here, the relator) must establish the defendant's knowledge of the falsity of the statement, which it can do by introducing evidence of how the statement would have been understood in context." *Minnesota Assoc. of Nurse Anesthetists v. Allina Health System Corp.*, 276 F.3d 1032, 1053 (8th Cir. 2002) (emphasis added). In the Minnesota case, the relator alleged that anesthesiologists billed Medicare as if they had "personally performed" an entire anesthesia case or were "continuously involved" in the performance of that case when, in fact, they were not continuously present during the case and were instead simultaneously engaged in other activities. *Id.* at 1037, 1038. A district court granted the defendants summary judgment because the court considered the Medicare regulation's phrases "personally performed" and "continuously involved" to be ambiguous. *Id.* at 1052-1053. The Eighth Circuit reversed, stating, "If the [relator] shows the defendants certified compliance with the regulation knowing that the HCFA interpreted the regulations in a certain way and that their actions did not satisfy the requirements of the regulation as the HCFA interpreted it, any possible ambiguity of the regulations is water under the bridge." *Id.* at 1053. The Eighth Circuit found that evidence presented by the relator (including the defendants' attorney's advice, HCFA memoranda, a bulletin published by the FI, and an American Society of Anesthesiologists newsletter) was relevant to a determination of the Medicare regulation's meaning and that there was a question of fact as to the defendants' understanding of the meaning of the regulatory language. *Id.* at 1053-54.

In opposition to LFM's motion for summary judgment, Walker presented provisions from the Medicare Carrier's

Manual in use during the relevant time period,[3] bulletins published by the FI (and received and maintained by LFM) that provide guidance on proper "incident to the service of a physician" billing, programs for seminars attended by LFM personnel that reviewed information on proper "incident to the service of a physician" billing, and copies of notes handwritten by LFM personnel documenting conversations between LFM administrative personnel and a billing consultant regarding the need for UPINs for physician assistants and nurse practitioners. Each of these pieces of evidence is relevant to the meaning of the Medicare

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[3] The parties agree that, throughout the time period relevant to this lawsuit (whatever that might be), the Medicare Carrier's Manual set forth five criteria for a service to be covered as "incident to the services of a physician." To be covered, a service must: (1) be an integral, although incidental, part of the physician's professional service; (2) be commonly rendered without charge or included in the physician's bill; (3) be of the type commonly furnished in physicians' offices or clinics; (4) be furnished under the direct personal supervision of a physician; and (5) be furnished by a physician or an employee of a physician. Medicare Carriers Manual Part 3, Claims Process Pub. 14-3 (MCM), § 2050, at 2-19.

The parties also agree that, since at least 1992, the MCM has defined "direct personal supervision in the office setting" to require that "the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services." MCM, § 2050.1.B. at 2-20.

The parties disagree, however, regarding the meaning of other language in the MCM, particularly the language in MCM, § 2050.2, that states "there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part, and there must be subsequent services by the physician of a frequency that reflects his or her continuing active participation in and management of the course of treatment." *Id.* at 2-21.

regulation at issue and LFM's understanding of that meaning. *See Gold*, 743 F.2d at 816 (Medicare Carrier's Manual and FI letter to provider properly admitted into evidence). Taken together, they are sufficient to support findings that the Medicare regulation required that a physician be physically present in the office suite and otherwise more involved in a patient's course of care than the LFM physicians were and that LFM knew of these requirements. Thus, they raise an issue of fact as to the falsity of LFM's billing for nurse practitioner and physician assistant services "incident to the service of a physician." Summary judgment was inappropriate.

B. The Limit on Discovery

Walker also challenges the district court's decision to limit discovery in the case to the date range of her employment as a nurse practitioner at LFM. She correctly states that, if, in limiting the temporal scope of discovery, the district court "made a clear error of judgment . . . or . . . applied an incorrect legal standard," we must reverse that decision. *Peat, Inc. v. Vanguard Research, Inc.*, 378 F.3d 1154, 1159 (11th Cir. 2004) (citing *Alexander v. Fulton County*, 207 F.3d 1303, 1326 (11th Cir. 2000)).[4]

We find that the district court misconstrued the False Claims Act when it limited discovery to the term of Walker's employment. We therefore reverse the discovery order. Under the False Claims Act, any person may serve as a *qui tam* relator. 31 U.S.C. § 3730(b). The relator need not have any relation at all to the defendant. *Id.* Neither is there a requirement that the relator suffer injury at the hands of the defendant in order to state a claim under the False Claims Act. *Id.* "The United States is the real party in interest in a qui tam

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[4] Walker raised this issue in her initial brief, but LFM did not respond or otherwise address the argument in any of its briefing.

action under the FCA even if it is not controlling the litigation." *United States ex rel. Dimartino v. Intelligent Decisions, Inc.*, 308 F.Supp. 2d. 1318, 1322 n.8 (M.D. Fla. 2004) (citing *United States ex rel. Rodgers v. Arkansas*, 154 F.3d 865, 868 (8th Cir.1998); *United States ex rel. Hyatt v. Northrop Corp.*, 91 F.3d 1211, 1217 n. 8 (9th Cir.1996); *United States ex rel. Milam v. University of Texas M.D. Anderson Cancer Center*, 961 F.2d 46, 48-49 (4th Cir.1992)).

Under the Federal Rules of Civil Procedure, discovery is limited to "matter[s], not privileged, that [are] relevant to the claim or defense of any party . . . . Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence." Fed. R. Civ. P. 26(b)(1). Thus, Walker should have been permitted discovery of all information relevant to her claims, on behalf of the United States, that false claims for payment were made by LFM.

An examination of the Amended Complaint, the operative pleading in this case, demonstrates that Walker alleges that LFM submitted false claims from at least the time of Walker's hiring[5] into the undefined future. Paragraph 11 of the Amended Complaint recounts a conversation that Walker allegedly had with LFM's office manager, Gail Mayer. As part of that conversation, Mayer allegedly told Walker that LFM "never" billed nurse practitioner and physician assistant services as independent services but rather always billed them as services "incident to the service of a physician" and that if

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[5] Walker argues that discovery should be allowed from as far back as 1994, when LFM first hired a physician assistant (a fact that Walker learned from deposition testimony of LFM's office administrator). However, the Amended Complaint does not make any allegation that a physician assistant or nurse practitioner was employed at LFM prior to February 1997.

LFM were to bill the nurse practitioner and physician assistant services as independent services, "it could not afford to employ [Walker]." Amended Complaint ¶ 11. The same paragraph further alleges, "LFM's Medicare billing practices did not change subsequent to [Walker's] conversation with Gail Mayer." *Id.* Paragraph 9 of the Amended Complaint states, "Since [Walker's] employment with LFM, LFM has employed at least two more nurse practitioners and two more physician's assistants." Thus, the Amended Complaint does not limit the allegations of false claims to the time period during which Walker was employed by LFM. Rather, it alleges an ongoing practice of false billing from the time Walker began working as a nurse practitioner at LFM, in February 1997. The proper temporal range for discovery is February 1997 through the date of the original complaint.

C. The Denial of the Motion to Dismiss

Finally, LFM cross-appeals, arguing that the district court erred in denying LFM's Federal Rule of Civil Procedure 12(b)(6) motion to dismiss the Amended Complaint. The motion was grounded on the assertion that the Amended Complaint failed to plead fraud with particularity as required by Federal Rule of Civil Procedure 9(b). We find this argument meritless.

This is not a case like *United States ex rel. Clausen v. Laboratory Corporation of America, Inc.*, 290 F.3d 1301 (11th Cir. 2002), in which a "corporate outsider" made speculative assertions that claims "must have been submitted, were likely submitted or should have been submitted to the Government." 290 F.3d at 1311. Neither is this case like *Corsello v. Lincare, Inc.*, 428 F.3d 1008 (11th Cir. 2005), in which we recently affirmed the district court's dismissal on the ground that the relator's complaint was deficient under Rule 9(b) because it "failed to explain why he believe[d] fraudulent claims were ultimately submitted." 428 F.3d at 1014.

Walker's complaint identifies her as a nurse practitioner who was employed at LFM. Amended Complaint ¶7. Walker alleges that, during her employment at LFM, she never had her own UPIN and that she was instructed each day "which doctor she would be billing under." Amended Complaint ¶¶ 11, 15. The Amended Complaint also alleges that Walker had at least one personal discussion with LFM's office administrator (identified in the complaint by name) during which the two women discussed that Walker did not have her own UPIN, whether Walker and the other nurse practitioners and physician assistants should have their own UPINs, that (according to the office administrator) LFM billed all nurse practitioner and physician assistant services as rendered "incident to the service of a physician," that (also according to the office administrator) LFM had "never" billed nurse practitioner or physician assistant services in another manner, and the propriety of the billing method. Amended Complaint ¶¶ 10-12. These allegations are sufficient to explain why Walker believed LFM submitted false or fraudulent claims for services rendered by nurse practitioners and physician assistants "incident to the service of a physician." Therefore, we affirm the district court's order denying LFM's motion to dismiss Walker's complaint.

VI. CONCLUSION

For the reasons stated above, we reverse the grant of summary judgment in favor of R&F Properties of Lake County, Inc., formerly known as Leesburg Family Medicine. We find no error in the district court's denial of R&F Properties of Lake County, Inc.'s motion to dismiss the Amended Complaint. Finally, we conclude that the district court erred in limiting the temporal scope of discovery and remand for further proceedings consistent with this opinion.

REVERSED AND REMANDED.

Appendix B

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
OCALA DIVISION

UNITED STATES OF AMERICA
ex rel., KARYN L. WALKER,

Plaintiff,

-vs- Case No. 5:02-cv-131-Oc-10GRJ

R & F PROPERTIES OF LAKE COUNTY, INC.,

Defendant.

ORDER

This *qui tam* action is before the Court for consideration of "Defendant's Motion for Summary Final Judgment with Incorporated Memorandum of Law" (Doc. 72), to which the Plaintiff has responded (Doc. 79). For the reasons set forth below, the Court has concluded that the Defendant's motion is due to be granted.

BACKGROUND

On May 6, 2002 the Plaintiff filed this action pursuant to the federal False Claims Act, 31 U.S.C. § 3729 *et. seq.* The United States declined to intervene (Doc. 14). On September 19, 2003, the Court entered an Order (Doc. 36) denying the Defendant's "Motion to Dismiss the Plaintiff's Complaint for Failure to Plead Fraud with Particularity" (Doc. 23). On December 8, 2003, after the Court held that the Plaintiff's

discovery request for Medicare claims documents from the Defendant should be limited to documents for services performed by the Plaintiff and any other nurse practitioner (as distinguished from services provided by a physician assistant) employed by the Defendant during the time period in which the Plaintiff was employed, the Plaintiff filed an amended complaint (Doc. 52). The amended complaint contains essentially the same allegations as those contained in the previous complaint, but it now includes allegations as to the medical services provided by "a physician's assistant" and "other nurse practitioners" (compare Doc. 1 with Doc. 52). On April 21, 2004, the Court issued an Order (Doc. 64) denying in all respects the Defendant's "Motion to Dismiss [the Plaintiff's] Amended Complaint and, Alternatively, to Certify to the Eleventh Circuit the Controlling Question Concerning the Sufficiency of the Amended Complaint" (Doc. 58).

The facts, as set forth in the Plaintiff's amended complaint, are as follows. The Defendant, R & F Properties of Lake County, Inc., formerly known as Leesburg Family Medicine (LFM), provides general and family medical services in Leesburg and Lady Lake, Florida. A majority of the Defendant's patients are covered by Medicare, a federally funded health insurance program. The Plaintiff was employed by the Defendant as a nurse practitioner from February 1997 to May 1999. The Plaintiff worked Monday through Friday from 8:00 a.m. to 5:00 p.m., and beginning in or around May 1997, she also worked one evening per week from 5:00 p.m. to 8:00 p.m., during which time she would provide services for 15 to 20 patients, and one Saturday per month from 8:00 a.m. to 5:00 p.m., during which time she would see an average of 20 patients.

The Plaintiff alleges that for the first few weeks of her employment she would present every patient's care plan to a

physician and receive feedback with respect to each patient. After the first few weeks of her employment had passed, the Plaintiff states that she did not present every patient she treated to one of the Defendant's physicians; rather, the Plaintiff alleges that of all of the patients that she treated, she only presented the "more serious, complicated cases." In fact, the Plaintiff contends that during her evening shifts and Saturday shifts she provided medical services to patients without any physician on site. Thus, the Plaintiff asserts that she was the sole provider of medical services to a majority of her patients. Despite this, the Plaintiff alleges that her services as a nurse practitioner were billed to Medicare as "incident to" the care of one of the Defendant's physicians.

The Plaintiff also states that during the entire period of her employment, the Defendant employed a physician's assistant, who worked the same evening and Saturday shifts as the Plaintiff. The Plaintiff asserts that "the physician's assistant and other nurse practitioners also saw new patients, and saw existing patients with new complaints, changing the patients' treatment plans and made new diagnoses" (Doc. 52).

The Plaintiff claims that in order to properly bill services provided to a Medicare beneficiary by a Mid-Level Care Provider, such as a physician's assistant or nurse practitioner, as "incident to" the services of a physician, the following conditions must be met: (1) a physician must be on site; (2) the services must be provided to an established patient with a condition that has been previously addressed by a physician along with a treatment plan devised by the physician; (3) the services must be provided in a follow up visit to the original diagnosis with no new symptoms; (4) the services to an existing patient cannot change the treatment plan in place; and (5) the services to an existing patient cannot result in a new diagnosis. The Plaintiff claims that the Defendant knowingly presented to the United States Government false

and fraudulent claims for reimbursement by billing the Plaintiff's services as "incident to" a physician's services even though on many occasions a physician was not on site when she provided services, she would see existing patients and change their treatment plans or make new diagnoses, and she would see new patients and make initial diagnoses and treatment plans.

The Defendant claims "there is no disputed issue of material fact as to whether [the Defendant's] claims to Medicare were false or fraudulent" (Doc. 72). The Defendant argues that the conditions required to bill for services "incident to" the care of a physician, as alleged by the Plaintiff, are not applicable to the time in question because Medicare law and regulations did not require the fulfillment of such conditions and the Medicare Carriers Manual, which contained such conditions, lacked the force and effect of law. In response, the Plaintiff argues that the Defendant's Motion fails to address important allegations in this action, therefore any ruling on this Motion will not be dispositive of the entire case (Doc. 79).[1] Additionally, the Plaintiff argues that the fundamental question in this case is not whether the Carriers Manual has the force and effect of law, but whether the Defendant filed a false claim.

SUMMARY JUDGMENT STANDARD

Pursuant to Federal Rule of Civil Procedure 56(c), the entry of summary judgment is appropriate only when the Court is satisfied that "there is no genuine issue as to any

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[1] The Plaintiff claims that the Defendant's Motion fails to address the allegation that the Defendant knowingly and improperly made claims to Medicare under the "incident to" provision for nonphysician services that were not actually incidental to any treatment provided by a physician. However, the Defendant addresses this claim in Doc. 72, page 8.

material fact and that the moving party is entitled to a judgment as a matter of law." In Celotex Corp. v. Catrett, the Supreme Court recognized that "the plain language of Rule 56(c) mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial."[2] The moving party bears the initial burden of establishing the nonexistence of a triable fact issue. If the movant is successful on this score, the burden of production shifts to the non-moving party who must then come forward with "sufficient evidence of every element that he or she must prove."[3] The non-moving party may not simply rest on the pleadings, but must use affidavits, depositions, answers to interrogatories, or other admissible evidence to demonstrate that a material fact issue remains to be tried.[4]

DISCUSSION

The False Claims Act was initially enacted to address the widespread fraud associated with Civil War defense contracts.[5] At that time, it was clear that the False Claims Act "was not designed to reach every kind of fraud practiced on the Government."[6] In 1986, the Act was substantially amended to address fraud in the areas of defense and

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[2] 477 U.S. 317, 322 (1986).

[3] Rollins v. Techsouth, Inc., 833 F.2d 1525, 1528 (11th Cir. 1987).

[4] Celotex, 477 U.S. at 324.

[5] See United States v. McNinch, 356 U.S. 595, 599 (1958).

[6] Id.

healthcare.[7] The 1986 amendments to the False Claims Act "modernizes jurisdiction and venue provisions, increases recoverable damages, raises civil forfeiture and criminal penalties, defines the mental element required for a successful prosecution and clarifies the burden of proof in civil false claims actions."[8] In essence, the amendments provide the Government with "a more useful tool against fraud in modern times" and "encourage[s] any individual knowing of Government fraud to bring that information forward."[9] Nonetheless, the penal nature of the False Claims Act requires careful scrutiny of any alleged misconduct under the statute[10] and the Act should not be used to "police technical compliance with administrative regulations."[11]

To establish a cause of action under 31 U.S.C.A. § 3729(a) of the False Claims Act, the Plaintiff must prove at least three elements: (1) a "false or fraudulent" claim (2) which was presented, or caused to be presented, by the Defendant to the United States for payment or approval (3) with knowledge that the claim was false. The dispositive issue in this case on summary judgment is whether the Plaintiff has introduced sufficient evidence to establish that the claims presented to the Government by the Defendant were false.

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[7] See S.Rep. No. 99-345, at 2-4, 8 (1986); reprinted in 1986 U.S.C.C.A.H. 5266, 5267-69, 5273.

[8] Id. at 2.

[9] Id.

[10] See U.S. ex rel. Weinberger v. Equifax, Inc., 557 F.2d 456, 460 (5th Cir. 1977).

[11] U.S. ex rel. Lamers v. City of Green Bay, 168 F.3d 1013, 1020 (7th Cir. 1999).

The "false or fraudulent" element is not defined by the False Claims Act. But the Second Circuit has described "false" to mean "not true," "deceitful," or "tending to mislead," and has described "fraud" as an "intentional misrepresentation, concealment, or nondisclosure for the purpose of inducing another in reliance upon it to part with some valuable thing belonging to him or to surrender a legal right."[12] In addition, the terms "false or fraudulent" in the False Claims Act "suggest an improper claim is aimed at extracting money the government otherwise would not have paid."[13] The Second Circuit recognized that a false claim may take different forms: a claim may be "factually false" if it "involves an incorrect description of goods or services provided or a request for goods or services never provided" or "legally false" if "a party certifies compliance with a statute or regulation as a condition to governmental payment" and then violates the applicable law.[14] A review of the amended complaint reveals that the Plaintiff contends that the claims submitted for her services were either factually false or legally false or both. With respect to the factually false claims, the Plaintiff alleges that she and other nonphysicians provided specific services, without the aid, assistance, or supervision of a physician, and that such services were then billed by the Defendant as if they were provided under the care or supervision of a physician. With respect to the legally false claims, the Plaintiff alleges that the Defendant contravened Medicare statutes and regulations by billing her services, as well as other nonphysicians' services, as "incident to" the services of a physician.

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[12] Mikes v. Straus, 274 F.3d 687, 696 (2d Cir. 2001) (citations omitted).

[13] Id.

[14] Id. at 697.

Legally False Claims

The Court concludes that the Plaintiff has failed to produce sufficient evidence to establish that the Defendant presented legally false claims to the Government either by billing nonphysician services as "incident to" the care of a physician when no physician was on site, or by billing nonphysician services as "incident to" a physician's involvement when nonphysicians provided initial diagnoses or changed treatment plans. During the relevant time period, between 1997 and 1999, neither the Medicare statutes nor the regulations provided much guidance on the level of supervision required in order to bill the services of a nurse practitioner or physician assistant as "incident to."[15] Therefore, the Plaintiff relies on the Medicare Carriers Manual to prove that the Defendant presented legally false

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[15] Pursuant to 42 U.S.C. § 1395k(a)(2)(B), the benefits provided to an individual under the Medicare Part B insurance program, which is the voluntary insurance program created pursuant to 42 U.S.C. § 1395j to provide medical insurance benefits for aged and disabled individuals, consist of, *inter alia*, "entitlement to have payment made on his behalf . . . for medical and other services . . . furnished by a provider of services." The definition of the term "medical and other health care services" includes "services and supplies . . . furnished as an incident to a physician's professional service, of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in the physicians' bills." 42 U.S.C. § 1395x(s)(2)(B) (emphasis added). The regulations promulgated by the Department of Health and Human Resources for the years 1997, 1998, and 1999 – the years of the Plaintiff's employment and the controlling years for this action – are equally unspecific in terms of defining "incident to." For example, 42 C.F.R. § 410.10(b) and 42 C.F.R. § 410.26(a) simply recite the language of 42 U.S.C. § 1395x(s)(2)(B).

claims.[16] The Court finds this evidence to be insufficient to withstand a motion for summary judgment because a failure to comply with the Carriers Manual guidelines does not sufficiently establish that the Defendant presented legally false claims to the Government.

According to the Centers for Medicare & Medicaid Services, or CMS, the entity within the Department of Health and Human Services charged with administering the Medicare program, the CMS program manuals "contain operating instructions, policies, and procedures based on

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[16] § 2050 of the Medicare Carriers Manual states that for services or supplies to be covered as "incident to the services of a physician, services and supplies must be: [a]n integral, although incidental, part of the physician's professional service (see § 2050.1); [c]ommonly rendered without charge or included in the physician's bill (see § 2050.1A); [o]f a type that are commonly furnished in physician's offices or clinics (see § 2050.1A); [f]urnished under the physician's direct personal supervision (see § 2050.1B); and [f]urnished by the physician or by an individual who qualifies as an individual of the physician. (See § 2050.1C)." § 2050.1 of the Carriers Manual further defines "Incident to Physician's Professional Services" as those services that are an "integral, although incidental, part of the physician's personal services in the course if diagnosis or treatment of an injury or illness." § 2050.1B of the Carriers Manual states "Direct Personal Supervision" means that "the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services."

§ 2050.2 describes the coverage available for the services of nonphysicians when they are furnished incident to a physician. In particular, the provision states that to have the service covered as incident to the services of a physician, "there must have been a direct, personal, professional service furnished by the physician to initiate the course of treatment of which the service being performed by the nonphysician practitioner is an incidental part . . ."

statutes and regulations, guidelines, models and directives."[17] CMS manuals address various topics and audiences, including hospitals, home health agencies, nursing facilities, intermediaries, carriers, and providers.[18] CMS defines a "carrier" as "a private company that has a contract with Medicare to pay your Medicare Part B bills."[19] In addition, CMS defines a "provider" as "[a]ny organization, institution, or individual that provides health care services to Medicare beneficiaries."[20] The Medicare Carriers Manual in particular "provides operating policies and procedures for contractors charged with administering the program . . . contains informational and procedural material the carrier needs for efficient processing and payment of claims . . . [and] includes instructions dealing with coverage of services, bill review, reasonable charges, and other pertinent claims procedures."[21]

The United States Supreme Court has held that the Medicare Provider Reimbursement Manual is an interpretive rule, which does not have the force and effect of law and is not accorded that weight in the adjudicatory process.[22] The Supreme Court has also held that "interpretations contained

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[17] Centers for Medicare & Medicaid Services, Medicare and Medicaid Paper-Based Manuals, at http://www.cms.hhs.gov/manuals/cmstoc.asp (last visited August 30, 2004).

[18] Id.

[19] Center for Medicare & Medicaid Services, Glossary, at http://www.cms.hhs.gov/glossary/default.asp?Letter=C&Language=English#Content (last visited August 30, 2004).

[20] Id.

[21] Centers for Medicare & Medicaid Services, Medicare and Medicaid Paper-Based Manuals, at http://www.cms.hhs.gov/manuals/cmstoc.asp (last visited August 30, 2004).

[22] Shalala v. Guernsey Memorial Hosp., 514 U.S. 87, 99 (1995).

in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law . . ." only warrant "some deference."[23] Consequently, the Carriers Manual, which is part of the same series of manuals issued by CMS as the Provider Reimbursement Manual, does not have the force and effect of law and should only be accorded some deference. Moreover, the Carriers Manual simply operates as a guideline for carriers in deciding whether or not to reimburse providers, it does not establish binding rules and regulations that providers must follow to avoid liability under the False Claims Act. Therefore, the Defendant in this case did not present a legally false or fraudulent claim to the Government by billing services as "incident to" the care of a physician solely because the Defendant contravened a manual that is directed toward carriers, not providers, and which should only be accorded "some deference."

The Plaintiff relies on In re Cardiac Devices Qui Tam[24] to establish that a violation of the Carriers Manual can result in liability under the False Claims Act. However, Cardiac Devices is distinguishable. The district court denied the defendants' motions to dismiss in that case because the defendant hospitals could face liability under the False Claims Act by violating provisions of the CMS Hospital Manual.[25] On the other hand, this case involves a motion for summary judgment on a claim that a provider failed to follow the guidelines set forth in a carriers manual.

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[23] Christensen v. Harris County, 529 U.S. 576, 587 (2000) (quoting EEOC v. Arabian Oil Co., 499 U.S. 244, 256-58 (1991)).

[24] 221 F.R.D. 318 (D. Conn. 2004).

[25] Id. at 353.

In United States ex rel. Swafford v. Borgess Medical Center, the plaintiff brought a claim under the False Claims Act against a group of doctors for improperly billing Medicare for venous ultrasound studies.[26] Like this case, the plaintiff relied on the Carriers Manual to establish that the doctors' claims were false.[27] The district court stated that the "Carriers Manual is merely a guide for fiscal intermediaries between Medicare and physicians, and lacks 'the binding effect of law or regulation' . . . Moreover, the Carriers Manual is intended to instruct carriers as to whether to play a claim and is not routinely provided to physicians."[28] In granting the defendant's motion for summary judgment, the district court "decline[d] to judge the truth or falsity of defendants' representations" based upon the Carriers Manual, which did not even "purport to address the physician's decision to submit a claim for reimbursement."[29]

The Plaintiff also argues that the Defendant presented legally false claims by violating an agreement with the Defendant's carrier, Blue Cross Blue Shield, and by not following the Medicare publications and training materials relating to "incident to" billing procedures. The Plaintiff alleges that the Defendant's agreement[30] with Blue Cross Blue Shield, which concerns the Defendant's submission of claims to Blue Cross Blue Shield via electronic media, establishes

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[26] 98 F. Supp. 2d 822, 825-26 (W.D. Mich. 2000), aff'd, 24 Fed. Appx. 491 (6th Cir. 2001), cert. denied, 535 U.S. 1096 (2002).

[27] Id.

[28] Id. at 828 (quoting in part National Medical Enterprises v. Bowen, 851 F.2d 291, 293 (9th Cir. 1988).

[29] Id.

[30] (Doc. 79, Exhibit A).

that the Defendant certified compliance with the Carriers Manual, thus making the Manual's "incident to" provisions applicable to the Defendant.[31] The Court finds this argument to be without merit. No where in the agreement does the Defendant explicitly agree to abide by the "incident to" provisions in the Carriers Manual, nor does the Defendant agree to comply with the entire manual to receive payment. The agreement simply states that payments may be adjusted according to the guidelines and the Defendant agrees to obtain the signature of each patient and use the signature in accordance with the guidelines.

Furthermore, the Plaintiff suggests that the Defendant can be held liable under the False Claims Act for not following Medicare publications[32] or training materials,[33] which state that a physician must be on site to bill services as "incident to" the care of a physician.[34] The Court concludes that the Defendant's apparent failure to follow these publications and training materials does not establish that the Defendant presented a legally false claim to the Government because not only do these materials lack the force and effect of law, but the Plaintiff has not presented any evidence that the Defendant agreed to comply with these materials in order to receive payment from the Government.[35]

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[31] (Doc. 79, page 4).

[32] (Doc. 79, Exhibit F).

[33] (Doc. 79, Exhibit D).

[34] (Doc. 79, page 5).

[35] See Mikes, 274 F.3d at 697, where the Second Circuit limited False Claims Act liability under a legally false claim certification theory to those situations where a party certifies compliance with the statute or regulation as condition of payment by the Government.

Consequently, the Medicare statutes, regulations, Carrier's Manual, and publications do not provide the plaintiff with sufficient evidence to support a finding that the Defendant presented legally false claims to the government.

Factually False Claims

The Plaintiff also alleges that the Defendant presented factually false claims by allowing the Plaintiff and other nonphysicians to render services, such as initial diagnoses and changed treatment plans, without the assistance of a physician and then bill such services as if they were under the care and supervision of a physician. The Court concludes that the plaintiff has also failed to introduce sufficient evidence to establish that the Defendant presented factually false claims by submitting an "incorrect description of goods or services provided" or making a claim for "services never provided."[36]

First, the Medicare insurance claim form used by the Defendant to submit claims simply states that

> [f]or services to be considered as "incident" to a physician's professional service, 1) they must be rendered under the physician's immediate personal supervision by his/or employee, 2) they must be an integral, although incidental part of a covered physician's service, 3) they must be of kinds commonly furnished in physician's offices, and 4) the services of nonphysicians must be included on the physician's bills.[37]

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[36] Id.

[37] See Health Insurance Claim Form, Form RRB-1500 (emphasis added).

The terms "immediate," "integral," and "incidental" are inherently imprecise and the Plaintiff has failed to present sufficient evidence that the Defendant's interpretation of the terms, that it was appropriate to have a physician immediately available by phone while treating patients or for nonphysicians to change treatment plans or offer diagnoses under the supervision of a physician, contravened the requirements of the form or the Medicare statutes and regulations, thus violating the False Claims Act.[38]

Second, Florida law supports a finding that the claims submitted by the Defendant were not factually false. Florida Statutes regulating the practice of medicine encourage physicians to more effectively utilize their specialized skills by "delegat[ing] health care tasks to qualified assistants when such delegation is consistent with the patient's health and welfare."[39] Moreover, Florida law defines "supervision" of a physician over his or her assistants as "responsible supervision and control" with "easy availability" to physician.[40] Florida law specifically establishes that the "term 'easy availability' includes the ability to communicate by way of telecommunication."[41] It is undisputed that the physicians

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[38] When statutes and regulations forming the basis of the Plaintiff's claims under the False Claims Act are ambiguous, the Plaintiff has the burden of proving that the statements made by the Defendant in presenting its claim for reimbursement were unreasonable. See, e.g., Luckey v. Baxter Healthcare Corp., 2 F. Supp. 2d 1034, 1049 (N.D. Ill. 1998).

[39] § 458.347(1)(a), Fla. Stat. (1997).

[40] § 458.347(2)(f), Fla. Stat. (1997).

[41] Id. See also, § 464.012(3), Fla. Stat. (1997), which sets forth the functions of nurse practitioners and Rule 64B9-4.001(14), Fla. Admin. Code (1999), which allows for nurse practitioners to perform procedures out of the presence of a physician as long as the practitioner can contact the physician by "communication devices."

in this case were always available by phone or pager to consult with the nurse practitioner or assistants on duty, as required by Florida law, thereby further supporting the finding that the Defendant did not submit factually false claims in this case.[42]

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[42] See Doc. 81, deposition of Karyn L. Walker.

CONCLUSION

Accordingly, upon due consideration, it is ordered:

(1) the Defendant's Motion for Summary Judgment (Doc. 72) is GRANTED.

(2) the Clerk is directed to enter judgment accordingly, terminate any pending motions, and close the files.

IT IS SO ORDERED.

DONE and ORDERED at Ocala, Florida this 6th day of October, 2004.

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United States District Judge

Copies to: Counsel of Record
Maurya McSheehy

Appendix C

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 04-15283

UNITED STATES, ex rel.,

Plaintiff,

KARYN L. WALKER,
a.k.a. Karyn L. Denk-Walker,

Plaintiff-Appellant
Cross-Appellee

Versus

R & F PROPERTIES OF LAKE COUNTY, INC.,
A Florida Professional Association,

Defendant-Appellee
Cross-Appellant.

On Appeal from the United States District Court for the
Middle District of Florida

ON PETITION(S) FOR REHEARING AND PETITION(S) FOR REHEARING EN BANC

Before: BIRCH, WILSON AND COX, Circuit Judges.

PER CURIAM:

The Petition(s) for Rehearing are DENIED and no Judge in regular active service on the Court having requested that the Court be polled on rehearing en banc (Rule 35, Federal Rules of Appellate Procedure), the Petition(s) for Rehearing En Banc are DENIED.

Appendix D

1. **Amendment V of the U.S. Constitution provides:**
Amendment V

No person shall be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation.

2. **Section 286 of Title 18, U.S.C. provides:**
§ 286 (2006). Conspiracy to defraud the government with respect to claims

Whoever enters into any agreement, combination, or conspiracy to defraud the United States, or any department or agency thereof, by obtaining or aiding to obtain the payment or allowance of any false, fictitious or fraudulent claim, shall be fined under this title or imprisoned not more than ten years, or both.

3. **Section 287 of Title 18, U.S.C. provides:**
§ 287 (2006). False, fictitious or fraudulent claims

Whoever makes or presents to any person or officer in the civil, military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.

4. Section 1001 of Title 18, U.S.C. provides:
§ 1001 (2006). Statements or entries generally

(a) Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;

(2) makes any materially false, fictitious, or fraudulent statement or representation; or

(3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry; shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both.

(b) Subsection (a) does not apply to a party to a judicial proceeding, or that party's counsel, for statements, representations, writings or documents submitted by such party or counsel to a judge or magistrate in that proceeding.

(c) With respect to any matter within the jurisdiction of the legislative branch, subsection (a) shall apply only to—

(1) administrative matters, including a claim for payment, a matter related to the procurement of property or services, personnel or employment practices, or support services, or a document required by law, rule, or regulation to be submitted to the Congress or any office or officer within the legislative branch; or

(2) any investigation or review, conducted pursuant to the authority of any committee, subcommittee, commission or office of the Congress, consistent with applicable rules of the House or Senate.

5. **Section 1002 of Title 18, U.S.C. provides:**
§ 1002 (2006). Possession of false papers to defraud United States

Whoever, knowingly and with intent to defraud the United States, or any agency thereof, possesses any false, altered, forged, or counterfeited writing or document for the purpose of enabling another to obtain from the United States, or from any agency, officer or agent thereof, any sum of money, shall be fined under this title or imprisoned not more than five years, or both.

6. **Section 3729 of Title 31, U.S.C. provides:**
§ 3729 (2006).

(a) **Liability for certain acts.**—Any person who—

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(4) has possession, custody, or control of property or money used, or to be used, by the Government and, intending to defraud the Government or willfully to conceal the property, delivers, or causes

to be delivered, less property than the amount for which the person receives a certificate or receipt;

(5) authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true;

(6) knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Government, or a member of the Armed Forces, who lawfully may not sell or pledge the property; or

(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus 3 times the amount of damages which the Government sustains because of the act of that person, except that if the court finds that—

(A) the person committing the violation of this subsection furnished officials of the United States responsible for investigating false claims violations with all information known to such person about the violation within 30 days after the date on which the defendant first obtained the information;

(B) such person fully cooperated with any Government investigation of such violation; and

> **(C)** at the time such person furnished the United States with the information about the violation, no criminal prosecution, civil action, or administrative action had commenced under this title with respect to such violation, and the person did not have actual knowledge of the existence of an investigation into such violation;

the court may assess not less than 2 times the amount of damages which the Government sustains because of the act of the person. A person violating this subsection shall also be liable to the United States Government for the costs of a civil action brought to recover any such penalty or damages.

(b) Knowing and knowingly defined.—For purposes of this section, the terms "knowing" and "knowingly" mean that a person, with respect to information—

> **(1)** has actual knowledge of the information;
>
> **(2)** acts in deliberate ignorance of the truth or falsity of the information; or
>
> **(3)** acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(c) Claim defined.—For purposes of this section, "claim" includes any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(d) Exemption from disclosure.—Any information furnished pursuant to subparagraphs (A) through (C) of subsection (a) shall be exempt from disclosure under section 552 of title 5.

(e) Exclusion.—This section does not apply to claims, records, or statements made under the Internal Revenue Code of 1986.

7. **Section 3730 of Title 31, U.S.C. provides:**
§ 3730 (2006). Civil actions for false claims

(a) Responsibilities of the Attorney General.—The Attorney General diligently shall investigate a violation under section 3729. If the Attorney General finds that a person has violated or is violating section 3729, the Attorney General may bring a civil action under this section against the person.

(b) Actions by private persons.—

(1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government. The action may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting.

(2) A copy of the complaint and written disclosure of substantially all material evidence and information the person possesses shall be served on the Government pursuant to Rule 4(d)(4) of the Federal Rules of Civil Procedure. The complaint shall be filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders. The Government may elect to intervene and proceed with the action

within 60 days after it receives both the complaint and the material evidence and information.

(3) The Government may, for good cause shown, move the court for extensions of the time during which the complaint remains under seal under paragraph (2). Any such motions may be supported by affidavits or other submissions in camera. The defendant shall not be required to respond to any complaint filed under this section until 20 days after the complaint is unsealed and served upon the defendant pursuant to Rule 4 of the Federal Rules of Civil Procedure.

(4) Before the expiration of the 60-day period or any extensions obtained under paragraph (3), the Government shall—

(A) proceed with the action, in which case the action shall be conducted by the Government; or

(B) notify the court that it declines to take over the action, in which case the person bringing the action shall have the right to conduct the action.

(5) When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.

(c) Rights of the parties to qui tam actions.—

(1) If the Government proceeds with the action, it shall have the primary responsibility for prosecuting the action, and shall not be bound by an act of the person bringing the action. Such person shall have the right to continue as a party to the action, subject to the limitations set forth in paragraph (2).

(2)

(A) The Government may dismiss the action notwithstanding the objections of the person initiating the action if the person has been notified by the Government of the filing of the motion and the court has provided the person with an opportunity for a hearing on the motion.

(B) The Government may settle the action with the defendant notwithstanding the objections of the person initiating the action if the court determines, after a hearing, that the proposed settlement is fair, adequate, and reasonable under all the circumstances. Upon a showing of good cause, such hearing may be held in camera.

(C) Upon a showing by the Government that unrestricted participation during the course of the litigation by the person initiating the action would interfere with or unduly delay the Government's prosecution of the case, or would be repetitious, irrelevant, or for purposes of harassment, the court may, in its discretion, impose limitations on the person's participation, such as—

(i) limiting the number of witnesses the person may call;

(ii) limiting the length of the testimony of such witnesses;

(iii) limiting the person's cross-examination of witnesses; or

(iv) otherwise limiting the participation by the person in the litigation.

(D) Upon a showing by the defendant that unrestricted participation during the course of the litigation by the person initiating the action would be for purposes of harassment or would cause the defendant undue burden or unnecessary expense, the court may limit the participation by the person in the litigation.

(3) If the Government elects not to proceed with the action, the person who initiated the action shall have the right to conduct the action. If the Government so requests, it shall be served with copies of all pleadings filed in the action and shall be supplied with copies of all deposition transcripts (at the Government's expense). When a person proceeds with the action, the court, without limiting the status and rights of the person initiating the action, may nevertheless permit the Government to intervene at a later date upon a showing of good cause.

(4) Whether or not the Government proceeds with the action, upon a showing by the Government that certain actions of discovery by the person initiating the action would interfere with the Government's investigation or prosecution of a criminal or civil matter arising out of the same facts, the court may stay such discovery for a period of not more than 60 days. Such a showing shall be conducted in camera. The court may extend the 60-day period upon a further showing in camera that the Government has pursued the criminal or civil investigation or proceedings with reasonable diligence and any proposed discovery in the civil action will interfere

with the ongoing criminal or civil investigation or proceedings.

(5) Notwithstanding subsection (b), the Government may elect to pursue its claim through any alternate remedy available to the Government, including any administrative proceeding to determine a civil money penalty. If any such alternate remedy is pursued in another proceeding, the person initiating the action shall have the same rights in such proceeding as such person would have had if the action had continued under this section. Any finding of fact or conclusion of law made in such other proceeding that has become final shall be conclusive on all parties to an action under this section. For purposes of the preceding sentence, a finding or conclusion is final if it has been finally determined on appeal to the appropriate court of the United States, if all time for filing such an appeal with respect to the finding or conclusion has expired, or if the finding or conclusion is not subject to judicial review.

(d) Award to qui tam plaintiff.—

(1) If the Government proceeds with an action brought by a person under subsection (b), such person shall, subject to the second sentence of this paragraph, receive at least 15 percent but not more than 25 percent of the proceeds of the action or settlement of the claim, depending upon the extent to which the person substantially contributed to the prosecution of the action. Where the action is one which the court finds to be based primarily on disclosures of specific information (other than information provided by the person bringing the action) relating to allegations or transactions in a

criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit, or investigation, or from the news media, the court may award such sums as it considers appropriate, but in no case more than 10 percent of the proceeds, taking into account the significance of the information and the role of the person bringing the action in advancing the case to litigation. Any payment to a person under the first or second sentence of this paragraph shall be made from the proceeds. Any such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(2) If the Government does not proceed with an action under this section, the person bringing the action or settling the claim shall receive an amount which the court decides is reasonable for collecting the civil penalty and damages. The amount shall be not less than 25 percent and not more than 30 percent of the proceeds of the action or settlement and shall be paid out of such proceeds. Such person shall also receive an amount for reasonable expenses which the court finds to have been necessarily incurred, plus reasonable attorneys' fees and costs. All such expenses, fees, and costs shall be awarded against the defendant.

(3) Whether or not the Government proceeds with the action, if the court finds that the action was brought by a person who planned and initiated the violation of section 3729 upon which the action was brought, then the court may, to the extent the court

considers appropriate, reduce the share of the proceeds of the action which the person would otherwise receive under paragraph (1) or (2) of this subsection, taking into account the role of that person in advancing the case to litigation and any relevant circumstances pertaining to the violation. If the person bringing the action is convicted of criminal conduct arising from his or her role in the violation of section 3729, that person shall be dismissed from the civil action and shall not receive any share of the proceeds of the action. Such dismissal shall not prejudice the right of the United States to continue the action, represented by the Department of Justice.

(4) If the Government does not proceed with the action and the person bringing the action conducts the action, the court may award to the defendant its reasonable attorneys' fees and expenses if the defendant prevails in the action and the court finds that the claim of the person bringing the action was clearly frivolous, clearly vexatious, or brought primarily for purposes of harassment.

* * *

8. Section 3731 of Title 31, U.S.C. provides:
§ 3731 (2006). False claims procedure

(a) A subpena [sic] requiring the attendance of a witness at a trial or hearing conducted under section 3730 of this title may be served at any place in the United States.

(b) A civil action under section 3730 may not be brought—

(1) more than 6 years after the date on which the violation of section 3729 is committed, or

(2) more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances, but in no event more than 10 years after the date on which the violation is committed,

whichever occurs last.

(c) In any action brought under section 3730, the United States shall be required to prove all essential elements of the cause of action, including damages, by a preponderance of the evidence.

(d) Notwithstanding any other provision of law, the Federal Rules of Criminal Procedure, or the Federal Rules of Evidence, a final judgment rendered in favor of the United States in any criminal proceeding charging fraud or false statements, whether upon a verdict after trial or upon a plea of guilty or nolo contendere, shall estop the defendant from denying the essential elements of the offense in any action which involves the same transaction as in the criminal proceeding and which is brought under subsection (a) or (b) of section 3730.

9. **Section 3732 of Title 31, U.S.C. provides:**
§ 3732 (2006). False claims jurisdiction

(a) Actions under section 3730.—Any action under section 3730 may be brought in any judicial district in which the defendant or, in the case of multiple defendants, any one defendant can be found, resides, transacts business, or in which any act proscribed by section 3729 occurred. A summons as required by the Federal Rules of Civil Procedure shall be issued by the appropriate district court and served at any place within or outside the United States.

(b) Claims under state law.—The district courts shall have jurisdiction over any action brought under the laws of any State for the recovery of funds paid by a State or local government if the action arises from the same transaction or occurrence as an action brought under section 3730.

10. Section 410.10 of Title 42, C.F.R. provides:
§ 410.10 (2006). Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

11. Section 410.26 of Title 42, C.F.R. provided: § 410.26 (2001). Medical and other health services: Included services.

Subject to the conditions and limitations specified in this subpart, "medical and other health services" includes the following services:

(a) Physicians' services.

(b) Services and supplies furnished incident to a physician's professional services, of kinds that are commonly furnished in physicians' offices and are commonly either furnished without charge or included in the physicians' bills.

(c) Services and supplies, including partial hospitalization services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

(d) Diagnostic services furnished to outpatients by or under arrangements made by a hospital or CAH if the services are services that the hospital or CAH ordinarily furnishes to its outpatients for diagnostic study.

(e) Diagnostic laboratory and X-ray tests (including diagnostic mammography that meets the conditions for coverage specified in § 410.34(b) of this subpart) and other diagnostic tests.

(f) X-ray therapy and other radiation therapy services.

(g) Medical supplies, appliances, and devices.

(h) Durable medical equipment.

(i) Ambulance services.

(j) Rural health clinic services.

(k) Home dialysis supplies and equipment; on or after July 1, 1991, epoetin (EPO) for home dialysis patients, and, on or after January 1, 1994, for dialysis patients, competent to use the drug; self-care home dialysis support services; and institutional dialysis services and supplies.

(l) Pneumococcal vaccinations.

(m) Outpatient physical therapy and speech pathology services.

(n) Cardiac pacemakers and pacemaker leads.

(o) Additional services furnished to enrollees of HMOs or CMPs, as described in § 410.58.

(p) Hepatitis B vaccine.

(q) Blood clotting factors for hemophilia patients competent to use these factors without medical or other supervision.

(r) Screening mammography services.

(s) Federally qualified health center services.

(t) Services of a certified registered nurse anesthetist or an anesthesiologist's assistant.

(u) Prescription drugs used in immunosuppressive therapy.

(v) Clinical psychologist services and services and

supplies furnished as an incident to the services of a clinical psychologist, as provided in § 410.71.

(w) Clinical social worker services, as provided in § 410.73.

(x) Services of physicians and other practitioners furnished in or at the direction of an IHS or Indian tribal hospital or clinic.

(y) Intravenous immune globulin administered in the home for the treatment of primary immune deficiency diseases.

12. Section 410.26 of Title 42, C.F.R. provides:
§ 410.26 (2006). Services and supplies incident to a physician's professional service: Conditions.

(a) Definitions. For purposes of this section, the following definitions apply:

(1) Auxiliary personnel means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner).

(2) Direct supervision means the level of supervision by the physician (or other practitioner) of auxiliary personnel as defined in § 410.32(b)(3)(ii).

(3) Independent contractor means an individual (or an entity that has hired such an individual) who performs part-time or full-time work for which the individual (or an entity that has hired such an individual) receives an IRS-1099 form.

(4) Leased employment means an employment relationship that is recognized by applicable State law and that is established by two employers by a contract such that one employer hires the services of an employee of the other employer.

(5) Noninstitutional setting means all settings other than a hospital or skilled nursing facility.

(6) Practitioner means a non-physician practitioner who is authorized by the Act to receive payment for services incident to his or her own services.

(7) Services and supplies means any services or supplies (including drugs or biologicals that are not usually self-administered) that are included in section 1861(s)(2)(A) of the Act and are not specifically listed in the Act as a separate benefit included in the Medicare program.

(b) Medicare Part B pays for services and supplies incident to the service of a physician (or other practitioner).

(1) Services and supplies must be furnished in a noninstitutional setting to noninstitutional patients.

(2) Services and supplies must be an integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

(3) Services and supplies must be commonly furnished without charge or included in the bill of a physician (or other practitioner).

(4) Services and supplies must be of a type that are commonly furnished in the office or clinic of a physician (or other practitioner).

(5) Services and supplies must be furnished under the direct supervision of the physician (or other

practitioner). The physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

(6) Services and supplies must be furnished by the physician, practitioner with an incident to benefit, or auxiliary personnel.

(7) A physician (or other practitioner) may be an employee or an independent contractor.

(c) Limitations.

(1) Drugs and biologicals are also subject to the limitations specified in § 410.29.

(2) Physical therapy, occupational therapy and speech-language pathology services provided incident to a physician's professional services are subject to the provisions established in § 410.59(a)(3)(iii), § 410.60(a)(3)(iii), and § 410.62(a)(3)(ii).

13. Section 410.32 of Title 42, C.F.R. provides:
§ 410.32 (2006). Diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests: Conditions.

* * *

(b) Diagnostic x-ray and other diagnostic tests —

(1) Basic rule. Except as indicated in paragraph (b)(2) of this section, all diagnostic x-ray and other diagnostic tests covered under section 1861(s)(3) of the Act and payable under the physician fee schedule must be furnished under the appropriate level of supervision by a physician as defined in section 1861(r) of the Act. Services furnished without the

required level of supervision are not reasonable and necessary (see § 411.15(k)(1) of this chapter).

(2) Exceptions. The following diagnostic tests payable under the physician fee schedule are excluded from the basic rule set forth in paragraph (b)(1) of this section:

(i) Diagnostic mammography procedures, which are regulated by the Food and Drug Administration.

(ii) Diagnostic tests personally furnished by a qualified audiologist as defined in section 1861(ll)(3) of the Act.

(iii) Diagnostic psychological testing services when —

(A) Personally furnished by a clinical psychologist or an independently practicing psychologist as defined in program instructions; or

(B) Furnished under the general supervision of a physician or a clinical psychologist.

(iv) Diagnostic tests (as established through program instructions) personally performed by a physical therapist who is certified by the American Board of Physical Therapy Specialties as a qualified electrophysiologic clinical specialist and permitted to provide the service under State law.

(v) Diagnostic tests performed by a nurse practitioner or clinical nurse specialist authorized to perform the tests under applicable State laws.

(vi) Pathology and laboratory procedures listed in the 80000 series of the Current Procedural Terminology published by the American Medical Association.

(3) Levels of supervision. Except where otherwise indicated, all diagnostic x-ray and other diagnostic tests subject to this provision and payable under the physician fee schedule must be furnished under at least a general level of physician supervision as defined in paragraph (b)(3)(i) of this section. In addition, some of these tests also require either direct or personal supervision as defined in paragraphs (b)(3)(ii) or (b)(3)(iii) of this section, respectively. (However, diagnostic tests performed by a physician assistant (PA) that the PA is legally authorized to perform under State law require only a general level of physician supervision.) When direct or personal supervision is required, physician supervision at the specified level is required throughout the performance of the test.

(i) General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the nonphysician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.

(ii) Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean

that the physician must be present in the room when the procedure is performed.

(iii) Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

* * *

14. Section 489.11 of Title 42, C.F.R. provides:
§ 489.11

(a) Action by CMS. If CMS determines that the provider meets the requirements, it will send the provider—

(1) Written notice of that determination; and

(2) Two copies of the provider agreement.

(b) Action by provider. If the provider wishes to participate, it must return both copies of the agreement, duly signed by an authorized official, to CMS, together with a written statement indicating whether it has been adjudged insolvent or bankrupt in any State or Federal court, or whether any insolvency or bankruptcy actions are pending.

(c) Notice of acceptance. If CMS accepts the agreement, it will return one copy to the provider with a written notice that—

(1) Indicates the dates on which it was signed by the provider's representative and accepted by CMS; and

(2) Specifies the effective date of the agreement.

(3)

No. 06-152

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In The

Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,

Petitioner,

v.

KARYN L. WALKER,

Respondent.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Eleventh Circuit

RESPONDENT'S BRIEF IN OPPOSITION

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TABLE OF CONTENTS

	Page
INTRODUCTION	1
I. THERE IS NO CONFLICT OR CONFUSION AMONG CIRCUIT COURTS WITH RESPECT TO THE DECISION MADE BY THE ELEVENTH CIRCUIT IN THIS MATTER	4
A. The Eleventh Circuit's Opinion in This Matter Does Not Address the Issue Petitioner Asks This Court to Review	6
B. The Eleventh Circuit's Opinion in This Matter Does Not Conflict With Other Circuit Court Criminal or Civil FCA Opinions	10
C. Petitioner's Suggestion That the Mere Ambiguity of a Law, Rule or Regulation, Without Regard to a Defendant's Knowledge is Contrary to the Intent of the FCA and Contrary to Requirements of Numerous Fraud Statutes Created by Congress	19
II. PETITIONER'S ARGUMENTS RELATING TO ALLEGED VIOLATIONS OF BASIC CONSTITUTIONAL AND COMMON LAW PRINCIPLES WERE NOT RAISED BELOW AND CANNOT BE ADDRESSED FOR THE FIRST TIME BY THE SUPREME COURT, BUT EVEN IF REVIEWABLE, THE ELEVENTH CIRCUIT'S OPINION HAS NOT IMPINGED UPON THE DUE PROCESS CLAUSE NOR VIOLATED COMMON LAW PRINCIPLES AS PETITIONER SUGGESTS	21
A. The Eleventh Circuit's Opinion is not Contrary To the Due Process Clause	22

TABLE OF CONTENTS – Continued

Page

B. The Eleventh Circuit's Opinion is not Contrary to The Rule of Lenity 23

C. The Eleventh Circuit's Opinion is not Contrary to the Principle of Interpreting an Ambiguous Provision Against the Drafter ... 24

IV. THERE IS NO FAR REACHING QUESTION OF EXCEPTIONAL IMPORTANCE IMPLICATED BY THE OPINION OF THE ELEVENTH CIRCUIT IN THIS MATTER WHICH REQUIRES SUPREME COURT REVIEW 25

CONCLUSION 27

TABLE OF AUTHORITIES

Page

CASES

Adickes v. S.H. Kress & Co., 398 U.S. 144, 90 S.Ct. 1598, 26 L.Ed.2d 142 (1970) 21

Clingman v. Beaver, 544 U.S. 581, 125 S.Ct. 2029, 161 L.Ed.2d 920 (2005) 21

Commercial Contractors v. United States, 154 F.3d 1357 (Fed. Cir. 1998) 11, 12

Cooper Industries, Inc. v. Aviall Services, Inc., 543 U.S. 157, 125 S.Ct. 577, 160 L.Ed.2d 548 (2004) 21

Hagood v. Sonoma County Water Agency, 81 F.3d 1465 (9th Cir. 1996) 13, 14, 15

Luckey v. Baxter Healthcare Corp., 2 F.Supp.2d 1034 (N.D.Ill. 1998) 16

Minnesota Association of Nurse Anesthetists v. Allina Health Systems, 276 F.3d 1032 (8th Cir. 2002) 11

Tyger Construction Company, Inc. v. the United States, 28 Fed. Cl. 35 (1993) 17

United States ex rel. Augustine v. Century Health Services, Inc., 289 F.3d 409 (6th Cir. 2002) 11

United States v. Bohonus, 628 F.2d 1167 (9th Cir. 1980), *cert. den.*, 447 U.S. 928, 100 S.Ct. 3026, 65 L.Ed.2d 1222 (1980) 20

United States ex rel. v. Borgess Medical Center et.al, 98 F.Supp.2d 822 (W.D.Mich. 2000) 15

United States ex rel. Crews v. NCCS Healthcare of Illinois, Inc., 460 F.3d 853 (7th Cir. 2006) 10

United States ex rel. Fallon v. Accudyne Corp., 921 F.Supp. 611 (W.D.Wis. 1995) 11

TABLE OF AUTHORITIES – Continued

Page

United States ex rel. Harrison v. Westinghouse Savannah River Co., 352 F.3d 908 (4th Cir. 2003) 11

United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013 (7th Cir. 1999) 15, 16

United States ex rel. Morton v. A Plus Benefits, Inc., 139 Fed.Appx. 980 (10th Cir. 2005) 10, 12

United States ex rel. Oliver v. Parsons Co., 195 F.3d 457 (9th Cir. 1999) 14

United States ex rel. Swafford v. Borgess Medical Center et al., 24 Fed.Appx. 491 (6th Cir. 2001) 14, 15

United States v. Daniels, 247 F.3d 598 (5th Cir. 2001) 20

United States v. President and Fellows of Harvard College, 323 F.Supp.2d 151 (D.Mass. 2004) 1

United States v. Rybicki, 354 F.3d 124 (2nd Cir. 2003) 19

STATUTES

18 U.S.C. § 157 19

18 U.S.C. § 1341 19

18 U.S.C. § 1346 19

31 U.S.C. §§ 3729-3733 2

RULES

Federal Rule of Civil Procedure 9(b) 26

INTRODUCTION

The petition for certiorari filed by R & F Properties of Lake County, Inc. ("R & F") includes a grab bag of arguments and contentions (including many that were not raised in the District Court or the Court of Appeals) which ignore and confuse facts of the case, the import of the Eleventh Circuit's Order and the proceedings below, which make review of this case by this Court inappropriate. Petitioner urges this Court to adopt a position that, in a False Claims Act ("FCA") action, once a court determines that the language contained in the relevant regulation or contract provision allegedly violated by conduct of the defendant is ambiguous, under no circumstances could liability for fraud attach. Under Petitioner's proposed standard, the actual knowledge or understanding of a regulation that can be considered ambiguous in any context by a defendant would be completely irrelevant. Petitioner suggests creation of a bright line rule that, if a provision is found to be ambiguous, regardless of whether an entity has an understanding of the regulation and acts purposefully or knowingly in contravention of that understanding of the regulation in order to obtain money it is not entitled to, no liability would attach.

Not ly does this suggestion fly in the face of the remedial and preventative purposes of the FCA, but if accepted, it could completely eviscerate any force or meaning of the FCA. Further, Petitioner's suggested rule could provide a roadmap for entities or individuals to be able to commit fraud against the United States government without the worry of liability if it can simply be said that the language of the applicable law, rule or regulation is ambiguous to someone in some context. Petitioner's suggested rule can simply not be reconciled with the

purpose of the FCA – to provide a significant deterrence incentive for entities to not commit fraud against the United States government.

Further, the question presented for review, as crafted by Petitioner, is not one that can be addressed given the facts in this matter and the current stage of the litigation. Petitioner's question presented, "Whether liability under the civil False Claims Act, 31 U.S.C. §§ 3729-3733, can be based on a reasonable interpretation of an ambiguous regulation or contractual provision," fundamentally assumes that there is no question of fact as to whether the entity being accused of fraud has a reasonable interpretation of a regulation or contractual provision, and further assumes that the reasonable interpretation or knowledge of the defendant would allow for legal non-fraudulent conduct by the defendant. In other words, the question, as presented, assumes that the entity accused of fraud not only has some reasonable interpretation, but that the reasonable interpretation is in accord with the actions of the entity and that the reasonable interpretation truly suggests that the defendant's conduct is in good faith compliance with what the defendant believes to be allowed by the law, rule or regulation.

In this case, the evidence taken in a light most favorable to Walker (as it must be at this summary judgment stage) suggests that R & F never had any understanding or interpretation of the regulation or contract provision in question other than an interpretation and understanding that would make its conduct of submitting its claims the way it did, fraudulent. Specifically, the evidence presented by Walker suggests that R & F understood the "incident to" provisions of the Medicare guidelines to require certain prerequisites before claiming services as "incident to." In

contrast to that reasonable understanding that R & F had, R & F actually claimed services provided as "incident to" without meeting those prerequisites. Thus, this case cannot even squarely address Petitioner's question raised for review because Petitioner's fundamental assumptions necessary to even get to the question raised are not present. Instead of deciding that fraud could be predicated upon a mere legal dispute as suggested by Petitioner, the Eleventh Circuit here has simply recognized that, if those facts suggested by Walker are believed by a jury, the jury could find that R & F violated the FCA. It is a simple and not so uncommon or remarkable decision and opinion relating to the sufficiency of the evidence at the summary judgment stage of a dispute.

Additionally, even if this case did present a situation where Petitioner's suggested question for review were ripe, Petitioner's urged position is not one that would be appropriate for judicial review. Petitioner is asking this Court to intervene and proscribe the intent of Congress in contravention of the words of the statute. If Congress intended that only the violation of a clear cut law, rule or regulation could provide liability under the FCA, regardless of actual understanding of the law, rule or regulation, Congress would have included such intent in the statute itself. It did not, and neither can this Court.

Clearing up this fundamental confusion as to what the Eleventh Circuit's opinion actually addresses (a not so unique summary judgment motion where a question of fact remains), it also becomes clear that no fundamental Constitutional or common law principles were violated as suggested by Petitioner. The Eleventh Circuit has simply declared that the evidence should go to a jury to determine whether R & F knew that it should have complied with the

prerequisites to the "incident to" provisions of the Medicare guidelines before submitting its claims although it did not do so. R & F will still get its opportunity to present admissible evidence to the jury suggesting that it had a contrary understanding of the regulation. If the jury determines that R & F did not understand the provisions in the manner suggested by Walker, then it will not be held civilly or criminally responsible. However, that is unmistakably a factual issue which the jury must be allowed to decide.

Last, with the understanding that the Eleventh Circuit's decision did nothing more than accept Walker's version of the disputed facts as true and declare that the issue should go to a jury, this case at this stage does not present an issue of fundamental importance such as to warrant the review of this Court. This is a not uncommon case where fraudulent action has been alleged, and a jury should be allowed to determine whether it finds the elements required to establish fraud. Thus, the petition for a writ of certiorari should be denied.

I. THERE IS NO CONFLICT OR CONFUSION AMONG CIRCUIT COURTS WITH RESPECT TO THE DECISION MADE BY THE ELEVENTH CIRCUIT IN THIS MATTER.

Petitioner suggests that there is a conflict among circuit courts relating to the basis for FCA liability specifically suggesting that, in direct conflict with the Eleventh Circuit's opinion in this case, some circuit courts have found that a regulation which is alleged to have been violated by a defendant's conduct cannot be found to be ambiguous in any way if that violation is to be a basis for FCA liability. Instead, a close review of the cases cited by

Petitioner and what those cases actually address indicates that there is no conflict among the circuit courts and that this case is simply one that is not uncommon, which presents a pure factual dispute as to whether the defendant knowingly submitted a false claim.

When a plaintiff or relator in a specific FCA claim action cannot present sufficient evidence to defeat a summary judgment motion to suggest that the defendant knew of the falsity of its claims, certainly summary judgment is appropriate. The Eleventh Circuit in this case found that this is not the case here. Walker did present evidence to suggest that R & F knew of the falsity of its claims. Petitioner ***does not*** challenge the Eleventh Circuit's finding of the existence of a genuine conflict as to the material factual question of R & F's knowledge of the falsity of its submissions of claims. However, Petitioner wants to ignore this issue and have this Court to use this opportunity to convert this pure factual question (whether R & F understood the "incident to" provisions of the Medicare guidelines to include certain requirements) into a legal question and, thus, preclude any factual argument to the jury as to R & F's knowledge.

This approach is wholly unsupported by any legal authority. Several of Petitioner's comments throughout the petition completely ignore this factual dispute and start from an assumption that the factual determination has been resolved ***in its favor***. This is simply not appropriate in summary judgment and is not what the Eleventh Circuit did. Further, there is no case cited by the Petitioner or otherwise found by Respondent to suggest that the mere fact that a judge could look at words and declare them to be ambiguous in some context would be determinative or even important in deciding whether evidence

presented in a specific matter could establish liability under the FCA. Instead, the fact that a statute can be seen to be ambiguous is, and has always been, simply evidence that a defendant might choose to present to a jury when it is asked to determine knowledge of falsity. It has not been held and should be seen to be determinative of a defendant's knowledge – a specific factual element required to be established in order for liability to attach.

A. The Eleventh Circuit's Opinion in This Matter Does Not Address the Issue Petitioner Asks This Court to Review.

As described above, a review of the Eleventh Circuit's opinion reveals that the question Petitioner asks this Court to review is not a question implicated by this case. Petitioner suggests that this matter presents a situation where there is "no dispute that the regulation allegedly violated was ambiguous and that R & F's interpretation of the ambiguous regulation was reasonable." This statement, however, is both inaccurate and misses the point of the Eleventh Circuit's opinion. Even if the ambiguity of the regulation were not disputed, any dispute as to whether R & F's interpretation of the regulation was reasonable or not without addressing R & F's actual interpretation is completely irrelevant. The crux of the Eleventh Circuit's opinion was a determination that Walker had presented sufficient evidence to suggest that R & F's knowledge and interpretation of the regulation and contract provision was exactly the same as Walker's knowledge and understanding, as well as the Medicare community's and the government's understanding, i.e., that certain requirements were mandatory if a Medicare provider wanted to properly submit a claim as "incident

to" the services of a physician. Certainly if that understanding is determined to be R & F's understanding, there is no dispute that it is reasonable. However, unless the factual finding is made as to what R & F's understanding or knowledge was, the reasonableness is of no import to a summary judgment determination.

On the contrary, in the petition, R & F starts from the opposite conclusion, i.e., that its own interpretation of the statute and contract provision were that the specific requirements were not necessary as suggested by Walker and the evidence she presented. Thus, R & F ignores the Eleventh Circuit's decision that the facts must be accepted in a light most favorable to Walker and that those facts support a conclusion that R & F knew that the guidelines set forth the specific requirements suggested by Walker. It is only in ignoring that Eleventh Circuit finding that Petitioner's argument makes sense. However, the Eleventh Circuit's opinions cannot be ignored when analyzing this matter.

Once again, although the Eleventh Circuit stated that the regulation at issue prior to 2002 was ambiguous, it never found that R & F's interpretation of the regulation was that the requirements suggested by Walker and the Medicare community were not in fact requirements. In fact, the Eleventh Circuit properly found that a jury could determine from the evidence that R & F's interpretation was exactly the same as Relator's, the Medicare community's and the United States' interpretation, i.e., that certain criteria were required prior to submitting a claim as "incident to" a physician's services, and that R & F submitted the claims anyway without meeting those criteria. Petitioner continues by claiming that, "the Eleventh Circuit never attempted to challenge the district

court's ruling by arguing that R & F's interpretation of the ambiguous regulation was somehow unreasonable." Instead, the Eleventh Circuit's entire opinion challenged the finding by the district court that R & F's interpretation has been established. The Eleventh Circuit made clear, that, as in any summary judgment case, it would be inappropriate to assume that R & F ever understood the regulation or contract provision to mean anything other than what Walker suggests the regulation and contract provision mean because there is factual evidence that a jury could believe which could support Walker's (the non-moving party's) position.

Yet another example of Petitioner's misunderstanding and confusion of the issues in this case is seen at page 21 of the petition which states that, "[t]he Eleventh Circuit held the case against R & F could go forward since the ***plaintiff could show that she had a reasonable regulatory interpretation***." This comment is quite pointedly and importantly inaccurate. Instead of making some determination that summary judgment is inappropriate because Relator's interpretation of the statute is reasonable, the Eleventh Circuit held that this case can go forward because the Relator can provide evidence ***that Petitioner knew*** the falsity of its claims and that ***Petitioner's understanding*** of the regulation and contract provision was that the requirements should have been met despite Petitioner admittedly not meeting the requirements. The Eleventh Circuit simply commented that if the Petitioner's knowledge is such that the undisputed actions were fraudulent, the ambiguity of the statute is irrelevant.

Thus, although there is another reasonable interpretation of the regulation which, if proven to be the interpretation of the Petitioner, would absolve Petitioner of

liability, at the summary judgment stage, the factual disputes here – a dispute as to what Petitioner actually knew must be resolved in favor of the non-moving party – preclude such an outcome. As explained in the petition, the core of the false claims alleged in this matter revolve around Medicaid regulations allowing physicians to charge for services of non-physician caregivers (nurse practitioners and physician assistants) to Medicaid patients as services "incident to" the services of the physician. This case is about false and fraudulent Medicare claims submitted by R & F, and the facts as set out by Walker establish that R & F knowingly and intentionally represented to the government that certain criteria were met with respect to these services when it knew that the criteria were in fact not met. By falsely certifying that these criteria were met, the government paid out monies to R & F that it would have not otherwise paid had it known that the criteria were not met.

In this matter, R & F does not challenge the Eleventh Circuit's finding that the facts presented by the Relator could be found by a jury to determine that this defendant actually knew that its submissions for reimbursement through the Medicare program were fraudulent. Instead, R & F urges that the determination of that fact remain irrelevant, and suggests that if there is a reasonable interpretation of the law, rule or regulation at issue, regardless of whether it is the defendant's interpretation, a knowing violation of that law rule or regulation cannot support a finding of liability. Not only is this interpretation against the very purpose of the False Claims Act (to prevent knowing fraud) and against the well-established legal principles of allowing a jury to make these factual determinations, Petitioner's suggestion that other Circuits

or District Courts have found other than this is misleading. Thus, the petition filed in this matter should be denied.

B. The Eleventh Circuit's Opinion in This Matter Does Not Conflict With Other Circuit Court Criminal or Civil FCA Opinions.

Petitioner suggests that this Court's review is necessary in this matter because of a conflict in the lower courts regarding "whether, and under what circumstances, an alleged failure to comply with an ambiguous regulation or contract can serve as the basis for a FCA violation." However, a close look at that question suggested by Petitioner that this Court review and the cases cited by Petitioner to support its conclusion that there is a split amongst lower courts reveals that there is, in fact, no split among lower courts on the issue identified. Further, even if there were a split amongst lower courts, review of the Eleventh Circuit's opinion in this case will not resolve the issue identified by Petitioner.

In fact, Petitioner's question, whether liability under the FCA can be based on a reasonable interpretation of an ambiguous regulation or contractual provision, has been uniformly answered by lower courts. The consistent answer is that when a defendant fails to comply with an ambiguous (or an unambiguous) regulation or contract provision, such a failure can serve as the basis for a FCA violation only when knowing submission of a false claim is established. This has been the standard to prove a FCA violation and it has been reiterated and reaffirmed consistently. *See, United States ex rel. Crews v. NCCS Healthcare of Illinois, Inc.*, 460 F.3d 853, 855-856 (7th Cir. 2006); *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139

Fed.Appx. 980, 982 (10th Cir. 2005); *United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 913 (4th Cir. 2003); *United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409, 413 (6th Cir. 2002); *Minnesota Association of Nurse Anesthetists v. Allina Health Systems*, 276 F.3d 1032 (8th Cir. 2002).

It has further been well-established that the scienter or knowledge element is a question of fact for a jury to determine. *See, United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908 (4th Cir. 2003); *United States v. President and Fellows of Harvard College*, 323 F.Supp.2d 151, 196 (D.Mass. 2004); *United States ex rel. Fallon v. Accudyne Corp.*, 921 F.Supp. 611 (W.D.Wis. 1995). A review of the Eleventh Circuit's opinion sought to be reviewed clearly reveals that it was simply determined, in accord with all known published opinions on this issue, that R & F's knowledge presents a genuine issue of material fact and thus is a triable issue which requires jury determination.

Petitioner suggests that in direct contrast to its description of the Eleventh Circuit's decision in this case, "[o]ther lower courts have adopted the diametrically opposite approach to ambiguity. . . ." and provides citations to cases which it claims stand for the proposition that fraud cannot be predicated on a mere expression of opinion or legal dispute. However, because of the fundamental misunderstanding of the Eleventh Circuit's decision in this matter, each of these cases is inapposite, and none actually conflict with the decisions made in this matter.

Petitioner relies heavily on a case from the Federal Circuit, *Commercial Contractors v. United States*, 154 F.3d 1357, 1366 (Fed. Cir. 1998), to support its contention that

there is a split among the circuits. Petitioner suggests that *Commercial Contractors* conflicts with the Eleventh Circuit opinion in this matter. However, the language highlighted by the Petitioner from *Commercial Contractors* perfectly illustrates the fallacies in Petitioner's position and in fact illustrates that there is no conflict. In *Commercial Contractors,* the Federal Circuit agrees with the Eleventh Circuit, and every other circuit that has squarely addressed this issue, in finding that liability can be appropriate even analyzing a violation of an ambiguous law, rule or regulation, if there is "some specific evidence of knowledge that the claim is false or of an intent to deceive." *Id.* at 1366. Similarly, Petitioner points to *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 Fed.Appx. 980, 984 (10th Cir. 2004), an FCA lawsuit that was dismissed under Rule 12(b)(6) which Petitioner claims stands for the proposition that FCA liability cannot be predicated upon the violation of an ambiguous statute. In *Morton*, the relator had alleged that the defendant made a false claim, i.e., that their son's medical expenses were not covered under the Medicare plan. *Id.* at 981. Relator did not allege that the defendant actually believed that the Morton's son's medical expenses were actually covered under the Medicare plan and that with that knowledge, the defendant made the false statement alleged. In fact, the complaint apparently alleged that A Plus Benefits, Inc., had a specific interpretation of the plan which the Morton's claimed was false. *Id.* at 983. Thus, the Tenth Circuit found that the mere disagreement about the terms of the plan cannot form a basis for False Claims Act liability. *Id.* at 983-984.

Unlike *Morton*, this matter against R & F has been decided by the lower courts at the summary judgment

phase, and the issue has been whether there was sufficient evidence presented to establish that R & F's understanding of the "incident to" provisions of the Medicare scheme was exactly the same as Walker's interpretation, i.e., that the criteria that were admittedly not met by R & F prior to submission of the claims at issue were, in fact, prerequisites in order to properly submit a claim as "incident to" the services of a physician. The Eleventh Circuit found that there was sufficient evidence to establish this as R & F's understanding. Thus, if a jury were to believe the evidence produced by Walker, it could be established that R & F knowingly submitted a claim in contravention of its understanding of the "incident to" provisions of the Medicare guidelines.

Another case cited by Petitioner allegedly supporting its position and allegedly standing for the proposition that no FCA liability can be founded upon the violation of an ambiguous statute is *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465 (9th Cir. 1996). However, in *Hagood*, the Ninth Circuit stated, "Even viewing Hagood's evidence in the most favorable light, that evidence shows only a disputed legal issue; that is not enough to support a reasonable inference that the allocation was *false* within the meaning of the False Claims Act." *Id.* at 1477. This finding does not support Petitioner's suggestion that a mere factual determination that a regulation is ambiguous should preclude any FCA liability regardless of knowledge. Again, instead, it supports the well-established and uncontroverted standard of requiring evidence at the summary judgment stage to support a conclusion that the claim submitted is false. *Hagood* simply did not present that evidence, and thus summary judgment was granted.

Further, three years later, the Ninth Circuit clarified any misunderstanding in *Hagood* (such as that of Petitioner) in *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457 (9th Cir. 1999). In *Oliver*, the Ninth Circuit stated:

> *Hagood* does not stand for the proposition that a "reasonable interpretation" of a regulation precludes falsity. *Hagood* involved the question of whether the defendant's submission of allocation costs under the Wather Supply Act gave rise to a false claim under the False Claims Act. In *Hagood*, the statute itself granted discretion in deciding the cost allocation that the plaintiff claimed was false.

Oliver, at 463 (*internal citations omitted*). Therefore, because the law, rule or regulation at issue is not discretionary, *Hagood* is inapplicable to the matter between Walker and Petitioner.

Petitioner also cites cases based on *Hagood*, without further analysis. For example, Petitioner suggests that *United States ex rel. Swafford v. Borgess Medical Center et al.,* 24 Fed.Appx. 491 (6th Cir. 2001), stands for the proposition that FCA liability can never attach over the mere interpretation of a regulation which has been declared ambiguous. The *Swafford* opinion cited is simply an opinion affirming a district court opinion. Further, like *Hagood*, it involved a discretionary determination. In the district court opinion, Swafford argues that the relevant Medicare guidelines relating to the interpretation of venious ultrasounds create a certain standard of care which Borgess Medical Center did not provide prior to requesting reimbursement for those services. The district court found that the guidelines in question were ambiguous even as

described in interpretive manuals which were written to clarify the provisions. *United States ex rel. v. Borgess Medical Center et al.,* 98 F.Supp.2d 822 (W.D.Mich. 2000). Further, the district court found that there was insufficient evidence that a jury could believe to establish that Borgess Medical Center knew that the regulations required a certain standard which it did not provide. *Id.* at 828. Thus, summary judgment was inappropriate. These factual intricacies are in direct contrast to the evidence offered by Walker in this matter which could establish that R & F knew that the "incident to" regulations required certain prerequisites which it did not follow. Thus, neither the *Swafford* district court's opinion nor the Sixth Circuit *Swafford* panel's decision conflicts with the Eleventh Circuit's opinion in this matter.

Petitioner also points to a Seventh Circuit Case, *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013 (7th Cir. 1999) to establish a split amongst the Circuit Courts. This is yet another case that merely cites *Hagood* and involves a discretionary decision. And again, the facts of *Lamers* do not support Petitioner's suggestion that this Court adopt a bright-line rule that if a statute can be decreed ambiguous in any way, no FCA liability can attach. The *Lamers* opinion insightfully points out that, in discussing the falsity of a claim when addressing a summary judgment motion in an FCA action, it is impossible to avoid the issue of knowledge. *Id.* at 1018. Then, the court looks at all evidence presented in a light most favorable to *Lamers* and concludes that, in that case, there was no evidence which a jury could believe to suggest that the City of Green Bay intended to violate the regulations. At most, the court determined that the relator had evidence of "a handful of technical violations committed by

individual drivers in a complex new busing program", and no evidence that the defendant had knowledge (as required under the FCA) of the falsity of the alleged claims. *Id.* at 1020. Again, this fact pattern is precisely distinct from the facts presented by Walker that could establish R & F's knowledge of the falsity of its claims, and also does not conflict with the Eleventh Circuit's opinion here.

Even the district court case cited by Petitioner, *Luckey v. Baxter Healthcare Corp.*, 2 F.Supp.2d 1034 (N.D.Ill. 1998), does not stand for the proposition Petitioner suggests. The *Luckey* court cites to a District of Minnesota case finding that, "ambiguous statutory requirements, where no regulations further define those requirements, cannot hold a defendant to the government's strict interpretation, so long ***as the defendant's interpretation was reasonable.***" *Id.* at 1049. (*emphasis added.*) The difference between this case against R & F and the case against Luckey is that in *Luckey*, apparently there was no dispute as to what the defendant's interpretation of the statute at issue was. In contrast, here there is a genuine issue of fact as to whether R & F's interpretation of the "incident to" provisions allowed for the conduct that engaged in or whether R & F interpreted the "incident to" provisions as Walker suggests it did, and thus, knew that its conduct was in contravention of those provisions. As *Luckey* once again highlights, courts consistently agree that the defendant's knowledge or understanding is a critical fact. Further, it is axiomatic that if a critical fact is in dispute, summary judgment is inappropriate.

In the final case cited by Petitioner, which supposedly suggests that a determination that a violation of any ambiguous provision can never form the basis for FCA liability, again does not support such a contention. In

Tyger Construction Company, Inc. v. the United States, 28 Fed. Cl. 35 (1993), the Federal Claims Court found that, although fraud cannot be predicated upon the mere expression of an opinion, if facts are established suggesting that a defendant knew that its claims were false, liability could attach. *Id.* at 56. Again, this interpretation is consistent with each of the other cases cited and with the Eleventh Circuit's opinion sought to be reviewed by Petitioner.

In its petition, R & F next lines up several cases which it suggests stand for the proposition that the ambiguity of an allegedly violated law rule or regulation does not automatically cut off the potential for FCA liability and which R & F claim are in direct contrast with the cases cited in the preceding several paragraphs. In describing these cases, R & F aptly describes the reasoning and holdings as emphasizing the fact that the defendant's knowledge and understanding of the ambiguous provision is of central importance. In this respect, Respondent agrees with Petitioner's assessment of those cases. However, what Petitioner misses is the same as what is described above – that there is not a single case presented where any court in the United States has gone as far as Petitioner suggests is appropriate. Because there is a genuine issue of fact as to what R & F's actual knowledge was in this matter, and because none of the cases which Petitioner suggests conflict actually deal with situations where there is no dispute as to the defendant's knowledge or interpretation, it is clear that they do not actually conflict with the Eleventh Circuit opinion here or any other opinion cited by R & F.

Ultimately, after analyzing the cases which Petitioner suggests provide a deep conflict among circuits, it is

apparent that, in fact, there is no conflict among the circuits, but that each factually distinct claim provides for distinct analyses and conclusions. At this stage, the case brought by Walker is not any more remarkable than the myriad of claims brought which uncover schemes of fraud by individuals and entities in an effort to manipulate the Medicare system. The Eleventh Circuit has simply found that it is appropriate to allow this matter to be decided by a jury, and if the jury determines that R & F knowingly submitted false claims, liability will attach. Petitioner suggests that "[o]nly the Supreme Court can end the confusion" and continues by suggesting that "[t]his Court should grant the petition and prevent FCA cases from going forward where the defendant has submitted a claim for reimbursement relying on a reasonable interpretation of an ambiguous regulation or contract." However, from an understanding of the facts in Walker and an analysis of all the case law presented, it is clear that there is no confusion or conflict. The current state of the law will not allow for a case to go forward where a defendant actually relies upon a reasonable interpretation of an ambiguous regulation or contract, even if that interpretation is seen by others to violate that regulation or contract provision. What Petitioner ignores is that in this matter, the evidence in a light most favorable to Walker suggests that R & F's interpretation of the regulation and contract were in conflict with how they actually acted. Thus, review of this matter would not even resolve a conflict, if it existed, in dealing with a factual scenario where it is not disputed that a FCA defendant's interpretation of a regulation or contract provision was such the defendant's actions were at least believed to be in compliance with the regulation or contract provision. Thus, because no conflict exists and because review of this case will not even implicate the

question presented by Petitioner for review, the Petition should not be granted.

C. Petitioner's Suggestion That the Mere Ambiguity of a Law, Rule or Regulation, Without Regard to a Defendant's Knowledge, is Contrary to the Intent of the FCA and Contrary to Requirements of Numerous Fraud Statutes Created by Congress.

If Petitioner's suggestion were accepted and a bright-line rule were declared establishing that a violation of any law, rule or regulation which has ambiguous language can never, as a matter of law, form a basis for fraud liability, not only would the FCA lose any meaning, but numerous other fraud statutes which Congress has enacted could be eroded. For example, Petitioner's suggestion that any statute upon which fraud liability is based must be completely unambiguous in order for a court to be able to go any further and consider actual intent to defraud. However, there are several examples of what can certainly be described as ambiguous statutes which, if violated, are consistently used as a basis for fraud liability or for criminal conviction. For example, the United States Congress has deemed it appropriate to enact laws making "mail fraud," "wire fraud," and "bankruptcy fraud" illegal. *See,* 18 U.S.C. § 157 (2006); 18 U.S.C. § 1341 (2006); 18 U.S.C. § 1346 (2006). These statutes includes words that can certainly be found to be ambiguous under certain circumstances and in certain contexts, but which federal courts have upheld as not unconstitutionally vague and as appropriate statutes upon which fraud convictions can attach. *See, e.g., United States v. Rybicki*, 354 F.3d 124, 143 (2nd Cir. 2003) (Wire fraud and mail fraud statutes

are not too vague or ambiguous to provide a basis for conviction if facts support knowing violation); *United States v. Daniels*, 247 F.3d 598, 600 (5th Cir. 2001) (Bankruptcy fraud statute is not too vague or ambiguous to provide a basis for conviction if facts support knowing violation); *United States v. Bohonus*, 628 F.2d 1167, 1173-1174 (9th Cir. 1980), *cert. den.*, 447 U.S. 928, 100 S.Ct. 3026, 65 L.Ed.2d 1222 (1980) (Mail fraud statute is not too vague to provide a basis for conviction if facts support violation.)

Understanding the context of Petitioner's argument, and understanding the far reaching implications of Petitioner's suggestion, makes clear just how inappropriate adoption of this standard would be. Certainly, the mere fact that the mail fraud statute contains ambiguous terms should not serve as a basis to allow every person ever accused of mail fraud to avoid liability or conviction even if we were faced with an unambiguous confession expressing a specific intent to commit that fraud. However, if this Court were to consider and adopt Petitioner's position, this outcome would extend therefrom.

The bottom line is that, taking away the inaccurate assumptions made by Petitioner and looking at the factual implications and issues that are clearly important in a fraud context, Petitioner's suggested standard in the context of fraud should not be accepted as such. The consistent approach to analyzing both criminal and civil fraud – regardless of the type of fraud – is to look to the factual determination of intent, a factual determination which must be allowed to be made if, as in this case, there is sufficient evidence that this fact is in dispute.

II. PETITIONER'S ARGUMENTS RELATING TO ALLEGED VIOLATIONS OF BASIC CONSTITUTIONAL AND COMMON LAW PRINCIPLES WERE NOT RAISED BELOW AND CANNOT BE ADDRESSED FOR THE FIRST TIME BY THE SUPREME COURT, BUT EVEN IF REVIEWABLE, THE ELEVENTH CIRCUIT'S OPINION HAS NOT IMPINGED UPON THE DUE PROCESS CLAUSE NOR VIOLATED COMMON LAW PRINCIPLES AS PETITIONER SUGGESTS.

In addition to its argument that the Eleventh Circuit's decision deepens existing conflict and confusion among the circuit courts as to the ability to generate FCA liability when confronted with an ambiguous regulation, Petitioner also argues, in its attempt to have this Court grant a writ of certiorari, that the decision below violates the Due Process Clause of the Constitution, as well as certain common law principles. None of these arguments were made by the Petitioner to either the district court or the Eleventh Circuit (including Petitioner's Petition for Rehearing or Rehearing *En Banc*).

This Court ordinarily does not consider or decide in the first instance issues not decided below. *Clingman v. Beaver*, 544 U.S. 581, 598, 125 S.Ct. 2029, 161 L.Ed.2d 920 (2005); *Cooper Industries, Inc. v. Aviall Services, Inc.*, 543 U.S. 157, 125 S.Ct. 577, 160 L.Ed.2d 548 (2004); *Adickes v. S.H. Kress & Co.*, 398 U.S. 144, 147, n. 2, 90 S.Ct. 1598, 26, L.Ed.2d 142 (1970). Therefore, none of these arguments should be considered by this Court as it determines whether to issue a writ of certiorari.

In the event this Court decides that it will, nonetheless, consider such arguments raised for the first time in Petitioner's petition for a writ of certiorari, the arguments

should be rejected. Because of the same fundamental misunderstanding of the Eleventh Circuit's ruling as it applies to the question of fact as to R & F's knowledge, none of Petitioner's arguments relating to due process, lenity or the rule of construction establish a basis upon which this Court should review this matter.

A. The Eleventh Circuit's Opinion is not Contrary To the Due Process Clause.

Petitioner spends several pages setting forth the standard of due process from the Constitution requiring that punishment should not be doled out unless the person being punished has notice of what he/she is being punished for. In principle, Petitioner's recitation of the application of the Due Process Clause in the civil context, as well as the criminal context, may well be accurate. However, the decision below does not impact any rights of the Petitioner under the Due Process Clause.

Petitioner only reaches its Due Process Clause argument by, again, misstating the holding of the Eleventh Circuit. On page 22 of its petition, Petitioner states that the decision below "violates the fair notice requirement of due process by holding a government contractor liable even if it is unaware of the falsity of its claim due to the regulatory ambiguity." Petitioner contends that it was faced with an ambiguous regulation and, therefore, crafted a reasonable interpretation of that regulation, which interpretation Petitioner claims guided its actions. This is not what Walker's evidence suggests occurred in this matter (which must be accepted as true for purposes of summary judgment) and, as stated above, this is not what the Eleventh Circuit determined. Walker presented

evidence that Petitioner was aware of the falsity of its claims and the court below simply determined that summary judgment was, therefore, inappropriate. To avoid summary judgment, Walker elicited evidence that *Petitioner's own interpretation* was consistent with that of the Medicare community and, therefore, Petitioner's claims, which failed to conform to such interpretation, were fraudulent. If Walker is unable to persuade the trier of fact that Petitioner had such an interpretation, but still acted contrary to such interpretation, i.e., that Petitioner was aware of the falsity, Walker will not prevail. Thus, if a jury determines that R & F did not have notice that its actions would subject it to liability, there will be no liability and no taking will occur to trigger substantive due process review. However, if Walker is successful in carrying her burden of persuasion, and a jury determines that R & F knew that its actions were in contravention of its own knowledge of the Medicare guidelines about "incident to" billing, Walker will prevail and an appropriate judgment will attach. The fact that either outcome is possible means that there has not been a violation of Petitioner's due process rights.

B. The Eleventh Circuit's Opinion is not Contrary to The Rule of Lenity.

Similarly, Petitioner claims that the decision below contravenes the rule of lenity which requires that criminal statutes (and, according to Petitioner, statutes of a penal nature such as the FCA) ensure fair warning by resolving ambiguity to apply only to conduct that is clearly within the reach of the statute. Again, as discussed above, the decision of the Eleventh Circuit can be found to have violated the rule of lenity only if one starts from the inaccurate facts assumed by the Petitioner in its petition.

In this case, at this stage, Walker has elicited evidence that would tend to prove that the Petitioner's assumptions stated in the Petition for a Writ of Certiorari are wrong, and therefore, as stated above, Petitioner had fair notice of the regulation, but still chose to file false claims. In the end, the trier of fact will determine who is correct.

C. The Eleventh Circuit's Opinion is not Contrary to the Principle of Interpreting an Ambiguous Provision Against the Drafter.

Again, the Petitioner's summary of the doctrine of *contra proferentum*, as described in the petition, appears accurate. However, any application of such doctrine to the facts of this matter is unwarranted. The argument would apply only if the facts were that Walker had failed to produce any evidence that showed Petitioner had an understanding of the requirements of the prerequisites necessary to support the claims it filed, but despite that understanding, still knowingly filed false claims. The decision below does not include a determination that the regulation at issue was ambiguous and that Walker and Petitioner simply reached two reasonable but differing interpretations. Had that been the case, it is possible that, were this Court to consider this argument, it might apply. However, as stated above, Walker's evidence is *not* that Petitioner had a second interpretation that differed from Walker's. Rather, her evidence is that Walker and Petitioner (as well as the Medicare community in general) had the same interpretation. Therefore, the doctrine of *contra proferentum* has no application to this matter were the Court to consider this argument in the first place.

IV. THERE IS NO FAR REACHING QUESTION OF EXCEPTIONAL IMPORTANCE IMPLICATED BY THE OPINION OF THE ELEVENTH CIRCUIT IN THIS MATTER WHICH REQUIRES SUPREME COURT REVIEW.

Petitioner further suggests that this case presents an issue of great importance because in Petitioner's estimation, FCA lawsuits are so overused that they provide a "trap for the unwary," and may force a defendant to litigate a lawsuit that it might ultimately prevail upon. Petitioner suggests that the Eleventh Circuit's opinion in this case "prevent[s] early dismissal of these FCA cases grounded on ambiguous regulations and contracts," and that somehow, FCA claims are too easy to prove or survive, forcing innocent defendants to pay large amounts of money to settle cases that should never be allowed to go forward. Petitioner suggests that a way to prevent this perceived abuse is to limit claims under the FCA only to fraudulent claims under unambiguous statutes.

Given the fundamental misunderstandings as described above, these assertions by Petitioner suggesting widespread abuse of the FCA and suggesting the devastating impact of the Eleventh Circuit's opinion in this matter if allowed to stand, paint a very misleading picture as to the ease of filing and prevailing as a relator under the FCA. First, the Eleventh Circuit's opinion in this matter is simply a decision reiterating the well accepted principles of summary judgment reaffirming that knowledge is a question of fact for a jury to determine. The opinion below does not stand for the proposition that FCA defendants can be held liable if their understanding of a law, rule or regulation is, in fact, reasonable and if that reasonable understanding equates to the actions of the defendant

being in good faith. Further, contrary to Petitioner's assertions, the mere fact that companies may have decided to voluntarily settle FCA claims might suggest that the company felt that it did something wrong and might not necessarily be a payoff to avoid the possibility of treble damages and penalties.

Such results are hardly "unfair and legally wrong" as suggested by Petitioner if the result is to repay to the government money that was fraudulently taken, particularly when Congress has expressed its clear intent that this fraud be dealt with by making bad actors pay treble damages and penalties. The "complex regulations and contracts" within the Medicare guidelines are hardly a "trap for the unwary" as suggested by Petitioner, and given the rigors of litigation, it would hardly be plausible to truly believe that a completely innocent company could be hoodwinked into settling a FCA claim for a large sum of money. The exacting standards of Federal Rule 9(b), as well as all the other requirements in place, including summary judgment standards, serve the litigation system well in ensuring that only true disputes as to material facts reach a jury. Simply because this matter happens to present a situation where there is, at the very least, believable evidence that R & F committed fraud, does not turn the Eleventh Circuit's opinion into one which will wreak havoc on all FCA defendants. Certainly, the exacting standards in place, which were created appropriately by Congress, will safeguard against any abuse of the system, and if Congress ever determines that it is appropriate to change the standards, it will do so.

Nothing in the petition for a writ of certiorari establishes a need for this Court to review the not so unusual circumstances in this matter left after the Eleventh

Circuit made a routine finding on a summary judgment issue and determined that a true factual dispute should be determined by a jury.

CONCLUSION

For the foregoing reasons, this Court should deny the petition for a writ of certiorari.

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In the Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY INC.,
F/K/A LEESBURG FAMILY MEDICINE,
Petitioner,

v.

UNITED STATES OF AMERICA *EX REL.* KARYN L. WALKER,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ii

REPLY BRIEF FOR THE PETITIONER 1

A. The Instant Case Squarely Presents The Question Posed In The Petition 2

B. The Lower Courts Are Split On Whether A Civil FCA Lawsuit Can Be Based On A Reasonable Interpretation Of An Ambiguous Regulation Or Contract 4

C. The Decision Below Is Contrary To The FCA And Violates Basic Constitutional And Common Law Principles 6

D. The Question Presented In This Case Is Far-Reaching And Of Exceptional Importance 9

CONCLUSION 10

TABLE OF AUTHORITIES

Cases

Cook County v. United States ex rel. Chandler, 538 U.S. 119 (2003) 8

Hagood v. Sonoma County Water Agency, 81 F.3d 1465 (9th Cir. 1996) 7

Minnesota Ass'n of Nurse Anesthetists v. Allina Health Sys., 276 F.3d 1032 (8th Cir. 2002) 3

United States v. Migliaccio, 34 F.3d 1517 (10th Cir. 1994) 6

United States v. Newport News Shipbuilding, Inc., 276 F. Supp. 2d 539 (E.D. Va. 2003) 4

United States ex rel. Lamers v. City of Green Bay, 168 F.3d 1013 (7th Cir. 1999) 4-5

United States ex rel. Swafford v. Borgess Med. Ctr., 24 Fed. Appx. 491 (6th Cir. 2001) 4

Vermont Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000) 8

REPLY BRIEF FOR THE PETITIONER

Respondent's opposition brief argues that, even if False Claims Act ("FCA") allegations are based on an objectively reasonable interpretation of an ambiguous regulation, the intent of the defendant is controlling and therefore any factual dispute over a contractor's knowledge precludes dismissal of an FCA action prior to trial. According to respondent, the Eleventh Circuit found a routine factual dispute regarding petitioner's knowledge and this unremarkable sufficiency of the evidence determination does not warrant review by this Court. Yet, along with mischaracterizing the decision below, respondent misses the entire point of the question presented in this petition. Consistent with the decisions of a number of lower courts, the petition argues that no FCA liability can attach to a claim submitted by a contractor based on a reasonable interpretation of an ambiguous regulation. Where the claim submitted to the government is an objectively reasonable interpretation of an ambiguous regulation or contract, a contractor is entitled to dismissal as a matter of law and the factual dispute regarding knowledge posited by respondent here is irrelevant.

Despite respondent's protestations to the contrary, the lower courts are split and confused on this question of the proper treatment of FCA allegations based on ambiguous regulations or contracts. Moreover, respondent's opposition does not even address the direct conflict noted in the petition between the decision below (and similar cases) and numerous criminal FCA cases. Respondent also fails to explain how submitting a claim based on an objectively reasonable interpretation of an ambiguous regulation or contract can ever rise to the level of fraud subjecting a

contractor to the FCA's punitive penalties and treble damages. Also, respondent cannot convincingly deny the exceptional importance of the question presented by this petition for FCA jurisprudence and all government contractors.[1]

A. The Instant Case Squarely Presents The Question Posed In The Petition

Respondent contends that this case is somehow not appropriate for addressing the question presented in the petition. The decision of the Eleventh Circuit, however, directly contradicts respondent, making clear that the court of appeals reversed the district court's dismissal based on its disagreement with the district court's conclusion that the ambiguous nature of the regulation precluded FCA liability as a matter of law:

> [T]he district court erred by holding that any ambiguity in the earlier version of 42 CFR § 410.26 and the HCFA 1500 certification necessarily forecloses, *as a matter of law*, the falsity of claims submitted by LFM prior to January 1, 2002. We agree that the regulatory language in effect until January 1, 2002 was ambiguous. But we disagree as to the *legal significance* of that ambiguity.

Pet. App. 12a (emphasis added). The appeals court's subsequent discussion concerning the implications of the

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[1] The significant and deleterious real-world impact of FCA allegations based on reasonable interpretations of ambiguous regulations and contracts also is highlighted in the briefs submitted in support of the petition by *amici curiae* Pharmaceutical Research and Manufacturers of America and the Washington Legal Foundation.

regulation's ambiguity, including its reliance on *Minnesota Ass'n of Nurse Anesthetists v. Allina Health Systems*, 276 F.3d 1032 (8th Cir. 2002), plainly goes directly to the question presented by this petition.

The instant case highlights the starkly different outcomes depending on how courts approach FCA allegations based on ambiguous regulations or contracts. If, as petitioner asserts, a claim based on an objectively reasonable interpretation of an ambiguous regulation or contract cannot rise to the level of fraud required for liability under the FCA, then these FCA lawsuits can be resolved in favor of defendants at an early stage. A court would be able to determine long before trial that the ambiguity relating to the claim submitted to the government makes the allegations inappropriate for proceeding under the FCA.[2]

By contrast, under respondent's theory, dismissal prior to trial would be impossible. Respondent would consider irrelevant the fact that the contractor's claim to the government was a reasonable interpretation of an ambiguous regulation or contract -- instead, the only issue for a court would be the knowledge of the defendant contractor. Yet, it is inherent in the very nature of *ambiguous* regulations or contracts that they might be interpreted contrary to a contractor's view -- a contractor will know that there is more than one reasonable interpretation, that the government has (or may adopt) a contrary view, and that the government's

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[2] The government could still seek to recover under breach of contract and other contractual and administrative theories if the contractor's interpretation is contrary to the government's interpretation. However, a contractor's objectively reasonable interpretation should not serve as the basis for fraud accusations and the imposition of punitive penalties and treble damages under the FCA.

interpretation may ultimately prevail. As a result, there invariably will be a factual dispute as to a defendant's knowledge that prevents a grant of summary judgment. *See* Pet. at 14 & n.10. Moreover, even without actual knowledge on the part of a defendant of the government's contrary interpretation, trial courts will deem granting summary judgment inappropriate because a factfinder "might conclude that [the defendant] acted with reckless disregard," which is sufficient knowledge for imposing liability under the FCA. *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 566 (E.D. Va. 2003); *see also* Pet. at 15-16 & n.11.

This petition raises the question and allows this Court to resolve the uncertainty as to which of these two different approaches should be used by the lower courts when faced with FCA allegations based on a reasonable interpretation of an ambiguous regulation or contract.

B. The Lower Courts Are Split On Whether A Civil FCA Lawsuit Can Be Based On A Reasonable Interpretation Of An Ambiguous Regulation Or Contract

Respondent contends that there is no split in the lower courts because all of the prior cases were decided based on whether a plaintiff offered evidence of a defendant's knowledge. Yet, what the lower courts have actually said belies this argument. As pointed out in the petition, there are numerous cases holding that "disputes as to interpretation of regulations do not implicate FCA liability." Pet. at 11-12 (quoting *United States ex rel. Swafford v. Borgess Med. Ctr.*, 24 Fed. Appx. 491, 491 (6th Cir. 2001)). These courts did not focus on the knowledge of the defendants. *See, e.g., United States ex rel. Lamers v.*

City of Green Bay, 168 F.3d 1013, 1018 (7th Cir. 1999) ("[I]mprecise statements or differences in interpretation growing out of a disputed legal question are similarly not *false* under the FCA.") (emphasis added). Although it is true that a line of lower court decisions considers a defendant's knowledge as determinative even where the alleged false claims involve a reasonable interpretation of an ambiguous regulation or contract, there plainly is no universally accepted standard or controlling test, and other courts have been unwilling to countenance FCA allegations based on disputes over ambiguous regulations or contracts.

In fact, the Eleventh Circuit's decision here does not even fit respondent's theory that a defendant's knowledge is controlling. Respondent contends that the key to the decision below was the Eleventh Circuit's purported conclusion that respondent had offered sufficient evidence of petitioner's wrongful knowledge. A careful reading of the decision, however, does not support respondent's analysis. The appeals court's opinion does not conduct a detailed examination of the deposition testimony or documents of petitioner's employees in order to determine petitioner's intent and state of mind. Rather, respondent submitted "provisions of the Medicare Carrier's Manual, Medicare bulletins, seminar programs, and expert testimony," and the circuit court carefully analyzed "whether any evidence outside the language of a Medicare regulation (including guidance issued by the governmental agency charged with administering the regulatory scheme) can be consulted to understand the meaning of that regulation." Pet. App. 12a-13a. This inquiry bears no relation to the knowledge of petitioner. Indeed, the court of appeals expressly stated that "[t]hus, they [the Manual, bulletins, seminar materials and experts] raise an issue of fact as to the *falsity* of [petitioner's] billing for nurse practitioner and physician assistant services

'incident to the service of a physician.'" *Id.* at 16a (emphasis added).

It also is noteworthy that respondent does not even attempt to reconcile the Eleventh Circuit's decision or her "knowledge" theory with the numerous criminal FCA cases cited in the petition. *See* Pet. at 16-21. As petitioner demonstrated, this Court has recognized that the civil and criminal FCA statutes historically grew up together and should be construed in a consistent fashion. Yet, in criminal FCA cases, "the government bears the burden to negate any reasonable interpretations that would make a defendant's statement factually correct where reporting requirements are ambiguous." *United States v. Migliaccio*, 34 F.3d 1517, 1525 (10th Cir. 1994); *see also* Pet. at 20 (and cases cited therein). As the *Migliaccio* standard indicates, these criminal FCA decisions do not look to a defendant's knowledge. Certiorari should be granted to resolve this conflict between the civil and criminal FCA cases on this important issue.

C. The Decision Below Is Contrary To The FCA And Violates Basic Constitutional And Common Law Principles

Respondent argues that petitioner's position "fl[ies] in the face of the remedial and preventative purposes of the FCA" and will "completely eviscerate any force or meaning of the FCA." Br. in Opp. at 1. This hyperbole is completely unsupported by any logic or case law.[3] Respondent does

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[3] Respondent states that petitioner's position is in "contravention of the words of the [FCA] statute." Br. in Opp. at 3. Yet, respondent never identifies what words those are. Congress nowhere specified in the FCA, nor does it appear in the legislative history, that claims based on ambiguous regulations fall within the statute's ambit.

not, and cannot, explain how a rule precluding FCA lawsuits based on a defendant's reasonable interpretation of an ambiguous regulation or contract is contrary to the language or purpose of the FCA. The FCA is aimed at frauds perpetrated by contractors against the United States. Submitting a claim that is a reasonable interpretation of an ambiguous regulation or contract may be "[taking] advantage of a disputed legal issue," *Hagood v. Sonoma County Water Agency*, 81 F.3d 1465, 1479 (9th Cir. 1996); it is not defrauding the United States. The submission of a claim based on a reasonable interpretation of an ambiguous regulation or contract cannot satisfy the falsity element under the FCA. A contractor also can never have the requisite wrongful intent when the claim submitted is reasonable and the regulation or contract ambiguous.[4] While a contractor's reasonable interpretation may ultimately be determined to be incorrect, thus resulting in the contractor owing money to the government, these actions do not rise to the level of a fraud that subjects a contractor to the FCA's draconian penalties and treble damages.[5]

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[4] Respondent creates a straw man by implying that petitioner is challenging the "knowingly" element of an FCA violation. Petitioner recognizes that this is an element under the Act and asserts that the wrongful knowledge requirement cannot be satisfied where the contractor submits a claim based on a reasonable interpretation of an ambiguous regulation or contract.

[5] Another wild charge by respondent is that petitioner advocates a "roadmap . . . to commit fraud . . . without the worry of liability if it can simply be said that the language of the applicable law, rule or regulation is ambiguous to someone in some context." Br. in Opp. at 1. This, of course, is a gross distortion of petitioner's position. FCA allegations are precluded only if the regulation or contract is ambiguous as specifically applied to a contractor's submission and only if a contractor's interpretation of the ambiguous regulation or contract is objectively reasonable. Additionally, in these circumstances, a contractor may nevertheless remain liable to the United States for contractual and

Respondent further argues that the Eleventh Circuit's decision ought to be affirmed because it furthers "the purpose of the FCA -- to provide a significant deterrence incentive for entities to not commit fraud against the United States government." Br. in Opp. at 1-2. But the threat of punitive FCA liability based on an objectively reasonable interpretation of an ambiguous regulation or contract only serves to chill contractors from engaging in legitimate disputes over regulatory and contractual meaning.[6] The United States should not receive a windfall, and a contractor should not be punished, because a regulation or contract is ambiguous. The United States has the ability to promulgate clear regulations and to draft clear contracts, and it has multiple administrative and contractual means to clarify vague provisions. Petitioner's approach would simply provide incentive for the government to write clear regulations and contracts and would create disincentives for the government and opportunistic *qui tam* relators seeking to use ambiguous regulations or contracts as the basis for filing strike suits and extracting settlements under the FCA.

Tellingly, respondent does not challenge the petitioner's description of the principles of fair warning under the Due Process Clause, the rule of lenity, and *contra proferentem*. Respondent concedes that these principles apply in the civil context where punitive sanctions, such as those imposed by the FCA, are at issue. Instead, respondent repeats her mantra about the circuit court's supposed finding

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administrative claims if its interpretation is later determined to be incorrect.

[6] This Court has recognized that the civil FCA is "essentially punitive in nature." *Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 784-85 (2000); *see also Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 120 (2003).

of a factual dispute about petitioner's knowledge, as if that were a talisman that wards off all other legal doctrines. Respondent ignores the Eleventh Circuit's clear holding that the "incident to" regulation was ambiguous. This ambiguity deprived petitioner of the fair warning required by due process and implicated the rule of lenity and the doctrine of *contra proferentem*. Where a contractor submits a claim that is a reasonable interpretation of an ambiguous regulation or contract, these constitutional and common law principles compel a ruling that the punitive FCA sanctions cannot be applied.

D. The Question Presented In This Case Is Far-Reaching And Of Exceptional Importance

Respondent cannot dispute the billions of dollars paid annually by the government to private contractors or that government contracts permeate virtually every industry in the American economy. Nor can she dispute the proliferation of FCA lawsuits brought by the United States and *qui tam* relators and the huge sums involved in these actions. The exceedingly complicated nature of the regulations and contracts governing most government contracts, such as the Federal Acquisition Regulation or Medicare regulations, also cannot be gainsaid. The confluence of these factors makes this petition involving FCA allegations based on ambiguous regulations or contracts of exceptional and ever-growing importance.

Respondent argues that this petition is not significant because it involves simply a "routine finding on a summary judgment issue." Yet, as discussed above, *supra* section A, the outcomes are dramatically different depending on how the question presented in the petition is decided. The practical impact of a ruling that allows plaintiffs to survive a motion to

dismiss in these cases involving ambiguous regulations and contracts cannot be overstated. Obtaining summary judgment on the issue of knowledge is exceedingly difficult, if not impossible. Faced with the cost and unpredictability of a jury trial and potentially devastating penalties and treble damages under the FCA, defendants invariably are forced into paying substantial settlements rather than gamble with going to trial. Such extortionate settlements in instances where a contractor submitted a claim based on an objectively reasonable interpretation of an ambiguous regulation or contract are unfair and poor public policy.

As noted by *amicus* Pharmaceutical Research and Manufacturers of America -- whose members must navigate complex Medicare and Food and Drug Administration regulations and are frequent targets of the United States and *qui tam* relators -- the enormous pressure for settlement makes the issue presented in this petition of a type that is capable of repetition but evading review. The question of the implications of ambiguous regulations and contracts for FCA liability is squarely presented by this petition. This Court should grant review to resolve the confusion in the lower courts and to make clear that a reasonable interpretation of an ambiguous statute or regulation cannot give rise to liability for fraud under the FCA.

CONCLUSION

For the reasons stated above and in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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No. 06-152

IN THE

Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,
F/K/A LEESBURG FAMILY MEDICINE,
Petitioner,

v.

UNITED STATES OF AMERICA *EX REL.* KARYN L. WALKER,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

MOTION FOR LEAVE TO FILE A BRIEF AS *AMICUS CURIAE* AND BRIEF OF *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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Petitioner,

v.

UNITED STATES OF AMERICA *EX REL.* KARYN L. WALKER,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

MOTION OF THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA TO FILE A BRIEF AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER

The Pharmaceutical Research and Manufacturers of America hereby requests, pursuant to Rule 37.2 of the Rules of this Court, leave to file the accompanying brief as *amicus curiae* in support of petitioner. PhRMA obtained the consent of petitioner.

The issue presented in this petition significantly affects PhRMA's interests and those of its members. PhRMA is a trade association that brings together the shared interests of the country's leading pharmaceutical research and biotechnology companies to accomplish common goals. PhRMA's primary mission is to advocate for public policies that encourage the discovery of life-saving and life-enhancing new

medicines by pharmaceutical research and biotechnology companies. PhRMA thus has a substantial interest in ensuring that the legal standards governing the pharmaceutical industry are stable, predictable, and consistent with sound public policy.

The question presented by this case is whether persons who submit claims to the government based on objectively reasonable interpretations of ambiguous statutes or regulations can be liable for fraud under the civil False Claims Act. This issue is critically important to the nation's pharmaceutical manufacturers, which in the last five years have become a primary target of FCA suits based on alleged violations of ambiguous rules. These suits have resulted in numerous multi-million dollar settlements. In the absence of a clear and uniform rule that FCA liability cannot be based on a reasonable interpretation of an ambiguous statute or regulation, manufacturers will continue to face enormous pressure to settle these cases in order to avoid the risk of exposure to the FCA's severe financial penalties. PhRMA thus has a vital interest in the issue presented in this case and its views can assist the Court in deciding whether certiorari should be granted.

For the foregoing reasons, PhRMA's Motion for Leave to File a Brief as *amicus curiae* should be granted.

Respectfully submitted,

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	ii
BRIEF OF *AMICUS CURIAE*	1
INTEREST OF THE *AMICUS CURIAE*	1
INTRODUCTION AND SUMMARY OF THE ARGUMENT	1
ARGUMENT	2
I. THE ISSUE RAISED BY THE PETITION IS EXCEEDINGLY IMPORTANT TO THE PHARMACEUTICAL INDUSTRY	2
A. Pharmaceutical Companies Have Become A Primary Target Of FCA Suits, Many Of Which Have Resulted In Enormous Settlements	2
B. FCA Suits Against Pharmaceutical Companies Are Often Based On The Alleged Violation Of Ambiguous Regulations	4
C. There Are Other Remedies Available To Ensure Compliance With Regulatory Requirements	14
II. THE DECISION BELOW IS WRONG, CREATES UNCERTAINTY, AND INCREASES THE INCENTIVE TO SETTLE MERITLESS FCA SUITS	16
CONCLUSION	20

TABLE OF AUTHORITIES

CASES Page

Nevada ex rel. Steinke v. *Merck & Co.*, 432 F. Supp. 2d 1082 (D. Nev. 2006) 11
Rehabilitation Ass'n of Va., Inc. v. *Kozlowski*, 42 F.3d 1444 (4th Cir. 1994) 6
United States v. *Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003) 17
Walker Process Equip., Inc. v. *Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965) 17
Washington Legal Found. v. *Henney*, 128 F. Supp. 2d 11 (D.D.C 2000) 13

STATUTES AND REGULATIONS

31 U.S.C. §§ 3729-3733 1
38 U.S.C. § 8126 5
42 U.S.C. § 1396r-8 ..... 5, 8, 9
§ 256b(a)(1) 4
48 C.F.R. § 33.210 16
§ 52.233-1 16
Medicaid Program; Drug Rebate Agreement, 56 Fed. Reg. 7049 (Feb. 21, 1991) 9, 10, 11, 15
Citizen Petition Regulating the FDA's Policy on Promotion of Unapproved Drugs & Devices, 59 Fed. Reg. 59,820 (Nov. 18, 1994) 13
Medicaid Program; Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Mfrs., 60 Fed. Reg. 48,442 (Sept. 19, 1995) (to be codified at 42 C.F.R. pts. 441 & 447 6
Final Guidance on Industry-Supported Scientific & Educational Activity, 62 Fed. Reg. 64,074 (Dec. 3, 1997) 12

TABLE OF AUTHORITIES – continued

Page

Prescription Drug Advertising & Promotional Labeling; Development & Use of FDA Guidance Document, 62 Fed. Reg. 14,912 (Mar. 28, 1997) 13

Decision in *Washington Legal Found.* v. *Henney*, 65 Fed. Reg. 14,286 (Mar. 16, 2000) 12

LEGISLATIVE HISTORY

136 Cong. Rec. S12954 (daily ed. Sep. 12, 1990) .. 10

SCHOLARLY AUTHORITIES

Jonathan K. Henderson & Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 Annals Health. L. 107 (2006) 2, 3, 17, 18

Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 Food & Drug L.J. 1 (2005) 3, 17, 18

Correy E. Stephenson, *Health Care Whistleblower Suits Are on the Rise*, Law. Wkly. USA, Nov. 21, 2005 ..... 3, 4

OTHER AUTHORITIES

Pharmaceutical Pricing Agreement (Mar. 24, 2005) (on file with author) 5, 15

SmithKline Whistleblowers Get $42.3 Million, Pa. L. Wkly., Apr. 20, 1998 18

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 14, Medicaid Drug Rebate Program Release (1994) 10

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 28, Medicaid Drug Rebate Program Release (1997) 7

TABLE OF AUTHORITIES – continued

Page

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 29, Medicaid Drug Rebate Program Release (1997) 7

Centers for Medicare & Medicaid Servs., Dep't of Health & Human Servs., No. 30, Medicaid Drug Rebate Program Release (1997) 7

The False Claims Act Legal Center, Top 20 Cases, *available at* http://www.taf.org/top20.htm 4

GAO, Report to Cong. Requestors, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States* (Feb. 4, 2005) 5, 6

Letter from Margaret M. Dotzel, Assoc. Comm'r for Policy, FDA, to Daniel J. Popeo and Richard A. Samp (Jan. 28, 2002), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/013002/01p-0250_pdn0001_01_vol2.pdf 12

Peter Keisler, Assistant Att'y Gen., Civil Division, U.S. Dep't of Justice, Remarks to the Taxpayers Against Fraud Education Fund Conference for Relators' Counsel, Washington, D.C. (Oct. 14, 2004) 3

Master Agreement Between The Sec'y of Veterans Affairs (Hereinafter Referred To As "The Sec'y") And The Mfr. Identified in Section VIII Of This Agreement (Hereinafter Referred To As "The Mfr.") (n.d) (on file with author) 5, 16

Office of the Inspector General, A-06-91-0092, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program* (Nov. 1992) 6

TABLE OF AUTHORITIES – continued

Page

Press Release, U.S. Dep't of Justice, Bayer Corporation and GlaxoSmithKline To Pay $344 Million To Resolve Allegations of Health Care Fraud Against State Programs (Apr. 16, 2003) (on file with author) 7, 9

Press Release, U.S. Dep't of Justice, Schering-Plough To Pay $345 Million To Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004) (on file with author) 7

Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty To Healthcare Crime; Company Agrees To Pay $355 Million To Settle Charges (June 20, 2003) (on file with author) 7

Press Release, U.S. Dep't of Justice, King Pharmaceuticals To Pay U.S. $124 Million For Medicaid Rebate Underpayments & Overcharging For Drug Products (Nov. 1, 2005) (on file with author) 7

Press Release, U.S. Dep't of Justice, Drug Giant Pfizer & Two Subsidiaries To Pay $49 Million For Defrauding Drug Medicaid Rebate Program (Oct. 28, 2002) (on file with author) 8

Press Release, U.S. Dep't of Justice, Warner-Lambert To Pay $430 Million To Resolve Criminal & Civil Health Care Liability Relating To Off-Label Promotion (May 13, 2004) (on file with author) 14

BRIEF OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America respectfully submits this brief as *amicus curiae* in support of petitioner.[1]

INTEREST OF THE *AMICUS CURIAE*

The interest of the *amicus curiae* is set forth in the accompanying motion for leave to file this brief.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The issue raised by this case is whether an entity that is subject to complex regulatory requirements can be held liable for engaging in fraud under the civil False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, when its actions are based on an objectively reasonable interpretation of an ambiguous statute or regulation. This issue is exceedingly important to the country's pharmaceutical manufacturers, which are subject to a host of extraordinarily complicated and often ambiguous statutes and regulations. The government has an array of tools at its disposal to clarify ambiguous statutory and regulatory requirements, as well as the power to require corrective actions by entities that acted on the basis of contrary but reasonable interpretations of those requirements. But in recent years, pharmaceutical companies have become a frequent target of *fraud* claims based on alleged violations of ambiguous statutes and regulations. In the absence of a clear and uniform rule that liability under the FCA – which predicates liability on the "knowing" submission of a false claim – cannot arise in such circumstances, many pharmaceutical companies face the Hobson's choice of agreeing to huge set-

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[1] Pursuant to Supreme Court Rule 37.6, *amicus* states that no person or entity other than *amicus*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief. Further, no counsel for either party has authored this brief in whole or in part.

tlements or litigating and risking exposure to the FCA's potentially devastating financial penalties.

The decision below is wrong and contrary to decisions issued by other federal courts. It is fundamentally unfair to hold a company liable *for fraud* where the company acted pursuant to an objectively reasonable interpretation of an ambiguous statute or regulation. The varying positions taken by the courts of appeals create an unacceptable level of uncertainty, and this uncertainty increases the substantial incentives FCA plaintiffs have to pursue fraud claims. It also increases the pressure on companies to settle such claims despite their reasonable belief that they have complied with the law. Such settlements impose a substantial cost on pharmaceutical companies, which inevitably reduces the resources available for research and development of new drugs and other productive activities.

For these reasons, the Court should grant the petition for certiorari in order to resolve the conflict among the circuits and to make clear that FCA liability cannot be premised upon a reasonable interpretation of an ambiguous statute or regulation.

ARGUMENT

I. THE ISSUE RAISED BY THE PETITION IS EXCEEDINGLY IMPORTANT TO THE PHARMACEUTICAL INDUSTRY.

A. Pharmaceutical Companies Have Become A Primary Target Of FCA Suits, Many Of Which Have Resulted In Enormous Settlements.

In the last five years, pharmaceutical manufacturers have become a primary target of qui tam lawsuits under the FCA.[2]

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[2] *See generally* Jonathan K. Henderson & Quintin Cassady, *Drug Deals in 2006: Cutting Edge Legal and Regulatory Issues in the Pharmaceutical Industry*, 15 Annals Health. L. 107, 107 (2006) ("The pharmaceutical industry as a whole has come under increased regulatory scrutiny by federal

Many of these suits have been premised upon pharmaceutical companies' alleged failure to comply with the complex – and frequently ambiguous – statutes and regulations governing the Medicare and Medicaid programs. And these suits have sent shockwaves throughout the industry, as companies have found themselves suddenly and unexpectedly exposed to potentially devastating liabilities for practices that they reasonably believed were entirely lawful. See, *e.g.*, Scheineson & Klinger, *supra*, at 7 (noting that "the evolving use by the government of the fraud and abuse laws" has "force[d] settlements by drug and device manufacturers for conduct that was, in large part, viewed by FDA and other agencies as acceptable industry practice until DOJ and OIG began to redefine the regulatory landscape.").

The recent surge in FCA litigation against pharmaceutical manufacturers is of particular concern to the industry given the magnitude of the liability that attaches to violations of the FCA, which provides for treble damages and a fine of between $5,500 and $11,000 per false claim. The combination of legal uncertainty and the FCA's severe financial penalties has frequently led manufacturers to settle FCA claims rather than contest them. It is not uncommon for these settlements to run into the hundreds of millions of dollars. See Henderson & Cassady, *supra*, at 114-23 (summarizing recent FCA cases in which manufacturers paid sums ranging between

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and state governments as well as the plaintiff's bar over the past several years."); Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 Food & Drug L.J. 1, 6 (2005) ("[T]he use of the FCA in pharmaceutical fraud and abuse actions has risen astronomically in the past five years."); Correy E. Stephenson, *Health Care Whistleblower Suits Are on the Rise*, Law. Wkly. USA, Nov. 21, 2005 (noting that health-care cases currently "dominate the qui tam landscape"); Peter Keisler, Assistant Att'y Gen., Civil Division, U.S. Dep't of Justice, Remarks to the Taxpayers Against Fraud Education Fund Conference for Relators' Counsel, Washington, D.C. (Oct. 14, 2004) (noting that, as of late 2004, there were approximately 100 whistleblower cases under seal involving allegations against over 200 drug manufacturers with respect to 500 different products).

$152 million and $560 million to settle FCA claims). In just nine of the largest FCA settlements by pharmaceutical companies in recent years, the companies involved paid an aggregate sum of nearly $3 billion. See The False Claims Act Legal Center, Top 20 Cases, *at* http://www.taf.org/top20.htm (last viewed Sept. 26, 2006). See also Stephenson, *supra* (noting that, of the $1.4 billion the United States recovered under the FCA in fiscal year 2005, $1.1 billion was associated with claims against health-care companies). In short, the amount of money the industry has at stake in these cases is staggering.

B. FCA Suits Against Pharmaceutical Companies Are Often Based On The Alleged Violation Of Ambiguous Regulations.

Many of the FCA claims that qui tam plaintiffs have brought against pharmaceutical companies in recent years have been based on the companies' alleged violation of ambiguous regulations. A full appreciation of the importance – and unfairness – of permitting FCA liability in such circumstances requires an understanding of the contractual and statutory contexts in which fraud claims against the pharmaceutical industry have arisen, and the ambiguities that have served as the basis for such claims.

Pharmaceutical manufacturers have numerous contractual relationships with government agencies, pursuant to which the manufacturers pay rebates, submit pricing information that establishes ceiling prices for certain categories of purchasers, or submit direct claims for payment. For example, under the terms of statutorily mandated contractual relationships, manufacturers report prices to the Health Resources and Services Administration that establish the ceiling price that may be charged to certain statutorily favored providers known as "340B" entities (*e.g.*, so-called "disproportionate share" hospitals and AIDS clinics). See 42 U.S.C. §

256b(a)(1).[3] Manufacturers likewise submit prices to the Department of Veterans Affairs ("VA") that establish the ceiling price that they generally must charge federal purchasers that acquire drugs off of the Federal Supply Schedule. See 38 U.S.C. § 8126.[4] Many manufacturers also contract directly to sell drugs to the VA, the Department of Defense, and other government agencies under the terms of standard government contacts.

The most significant contractual relationship between manufacturers and the government is the Medicaid Rebate Program. Under the terms of this program, manufacturers are obligated to pay the state Medicaid programs a quarterly rebate on each "covered drug," the magnitude of which is determined by the product of the "unit rebate amount" per unit of drug and the number of units reimbursed by each state during the relevant quarter. See 42 U.S.C. § 1396r-8(b)(1), (c)(1). Under the terms of the governing statute, manufacturers are obligated to enter into a contract – known as the standard Medicaid Drug Rebate Agreement ("MRA") – with the Centers for Medicare and Medicaid Services ("CMS"), which specifies the manufacturers' responsibilities and the government's remedies for breach. Collectively, manufacturers pay billions of dollars in rebates to the states every year. See, *e.g.*, GAO, Report to Cong. Requestors, *Medicaid Drug Re-*

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[3] Manufacturers' relationship with the government under the 340B Program is governed by a standard agreement with the Secretary of Health and Human Services. *See* Pharmaceutical Pricing Agreement § II(a) (Mar. 24, 2005) (on file with author) (requiring manufacturers "to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the [average manufacturer price] for the covered outpatient drug" less a defined "rebate percentage").

[4] Manufacturers' relationship with the government under the VA Program is governed by a standard agreement with the Secretary of Veterans Affairs. *See* Master Agreement Between The Sec'y Of VA (Hereinafter Referred To As "The Sec'y") And The Mfr. Identified In Section VIII Of This Agreement (Hereinafter Referred To As "The Mfr.") § II-B1 (n.d.) (on file with author) ("Master Agreement") (specifying the "'annual Federal ceiling price'" manufacturers may charge the VA for covered drugs).

bate Program: Inadequate Oversight Raises Concerns about Rebates Paid to States 1 (Feb. 4, 2005) (reporting that manufacturers paid $5.6 billion in rebates to the states in 2002).

The rules governing the Medicaid Rebate Program, like most of the rules governing the Medicare and Medicaid programs, are extraordinarily complex. See, *e.g.*, *Rehabilitation Ass'n of Va., Inc.* v. *Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (observing that the Medicare and Medicaid statutes and regulations "are among the most completely impenetrable texts within human experience"). Pursuant to the rebate statute, for example, the unit rebate amount a manufacturer must pay each quarter to each state is generally based on the difference between two prices – the "average manufacturer price" ("AMP") and the "best price" – and manufacturers are required to report these prices to the federal government. The ambiguities in the statutory definitions of both AMP and "best price" are well-documented and have never been clarified by regulation: In the fifteen years since the inception of the program, CMS has proposed rules once (in 1995), but never finalized them. See Medicaid Program, Payment for Covered Outpatient Drugs Under Drug Rebate Agreements with Mfrs., 60 Fed. Reg. 48,442 (Sept. 19, 1995).

The lack of official guidance is a frequently cited problem for the administration of the rebate program. Indeed, last year the Government Accountability Office ("GAO") noted that "neither the rebate statute nor CMS had provided sufficiently detailed instructions on methods for calculating AMP." GAO, *supra*, at 13. GAO accordingly "recommended that [the Administrator of] CMS issue clear, updated guidance on manufacturer price determination methods" and the definitions of best price and AMP. *Id.* at 5. See also Office of the Inspector General, A-06-91-00092, *Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Imple-*

ment the Program (Nov. 1992) (criticizing the lack of guidance regarding the definition of AMP).[5]

This lack of guidance, however, has not deterred qui tam plaintiffs from claiming that drug manufacturers have defrauded the government by incorrectly calculating their AMPs and "best prices." Such claims have led to many large FCA settlements.[6]

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[5] While CMS has never issued formal regulations, it has issued more than 80 program memoranda purporting to explain the provisions of the Medicaid Rebate statute. In many cases, such informal guidance has only exacerbated the problem. For example, in one release CMS attempted to clarify when manufacturers are required to include rebates offered to pharmacy benefit managers ("PBMs") in their AMP and "best price" calculations. *See* CMS, HHS, No. 28, Medicaid Drug Rebate Program Release, at 1 (1997). This release generated substantial confusion, so CMS issued another release purporting further to clarify its position. *See* CMS, HHS, No. 29, Medicaid Drug Rebate Program Release, at 1 (1997) ("The following item clarifies the information on the BP and AMP for PBMs provided in the Medicaid Drug Rebate Program Release No. 28."). When that release failed to resolve the issue, CMS issued yet another release acknowledging the confusion it had created and stating that it was "currently re-examining the issue and hope[d] to clarify [its] position in the near future." CMS, HHS, No. 30, Medicaid Drug Rebate Program Release, at 2 (1997). That release was issued in 1997, but CMS has yet to clarify its position.

[6] *See* Press Release, U.S. Dep't of Justice, Bayer Corp. & GlaxoSmithKline To Pay $344 Million To Resolve Allegations of Health Care Fraud Against State Programs (Apr. 16, 2003) (on file with author) (hereinafter Bayer/GlaxoSmithKline Press Release) (alleging that Bayer and GlaxoSmithKline failed to include the price of certain "private-label" sales in their best price reports for various drugs); Press Release, U.S. Dep't of Justice, Schering-Plough To Pay $345 Million To Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin (July 30, 2004) (on file with author) (alleging that Schering-Plough failed to account for certain discounts in its best price reports for Claritin); Press Release, U.S. Dep't of Justice, AstraZeneca Pharmaceuticals LP Pleads Guilty To Healthcare Crime; Company Agrees To Pay $355 Million To Settle Charges (June 20, 2003) (on file with author) (alleging that AstraZeneca failed to include certain price concessions in its best price reports for Zoladex); Press Release, U.S. Dep't of Justice, King Pharmaceuticals To Pay U.S. $124 Million For Medicaid Rebate Underpayments & Overcharging For Drug

For example, a number of settlements have grown out of the uncertainty over whether so-called "private-label" sales must be included in pharmaceutical companies' "best price" reports. "Best price" is defined by statute to be "the lowest price available from *the manufacturer* during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States," with specified exceptions. 42 U.S.C. § 1396r-8(c)(1)(C)(i) (emphasis added).

The definition of "best price" thus hinges on which company is deemed the "manufacturer" of a given drug. Unfortunately, the statute's use of the term "manufacturer" is ambiguous. Under the statutory definition, a "manufacturer" is, essentially, any entity that produces the drug or any entity that packages, labels, or distributes it.[7] Typically, both prongs of the definition identify the same entity as the "manufacturer" because a single entity produces, packages, labels, and distributes the drug.

This is not always the case, however. When one entity produces the drug and another packages, labels, or distributes it, there are two statutory "manufacturers" of the drug. This creates an anomaly, as the statutory definition of "best price" refers to the lowest price available from "the manufacturer"

Products (Nov. 1, 2005) (on file with author) (alleging that King failed to report accurately the AMP and best price for its Medicaid-reimbursed drugs); Press Release, U.S. Dep't of Justice, Drug Giant Pfizer & Two Subsidiaries To Pay $49 Million For Defrauding Drug Medicaid Rebate Program (Oct. 28, 2002) (on file with author) (alleging that Pfizer failed to include certain cash discounts in its best price report for Lipitor).

[7] "Manufacturer" is defined in full as "any entity which is engaged in—(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or (B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under state law." 42 U.S.C. § 1396r-8(k)(5).

and clearly contemplates that only one entity will have a rebate obligation.

Taking guidance from the Medicaid Drug Rebate Agreement CMS published in the Federal Register, pharmaceutical companies could reasonably resolve this well-documented statutory ambiguity by concluding that the "manufacturer" is the company that owns the National Drug Code ("NDC") number for the drug.[8] Accordingly, these companies would not include in their "best price" report the prices they offered for drugs sold pursuant to so-called "private-label" arrangements, *i.e.*, arrangements whereby the company agrees to produce the drugs under the customer's NDC number, and the customer distributes the drugs and in some cases repackages or relabels them. Quite reasonably, the companies following this interpretation would not consider themselves the "manufacturers" of the private-label drugs because they do not own the NDC numbers for those drugs.

Nonetheless, qui tam relators have filed suits alleging that these companies defrauded the government by not including private-label sales in their "best price" reports. In April 2003, for example, Bayer Corporation and GlaxoSmithKline agreed to pay a total of $344 million to settle an FCA case based on allegations of the companies' failure to include the prices of their private-label sales in their "best price" reports. See Bayer/GlaxoSmithKline Press Release.

Another issue arising out of the Medicaid Rebate Program is the scope of the "nominal price" exception to the definition of "best price." The rebate statute provides that "[t]he term 'best price' . . . shall not take into account prices that are merely nominal in amount." 42 U.S.C. § 1396r-8(c)(1)(C)(ii)(III). However, the statute does not define what amounts

[8] The Medicaid Drug Rebate Agreement specifies that the term "manufacturer" has the meaning set forth in the statute, "except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug." MRA § I(l), 56 Fed. Reg. 7049, 7051 (Feb. 21, 1991).

are "merely nominal"; nor does it define the entities that are eligible to receive such pricing. In the face of this statutory silence, the Secretary of Health and Human Services has interpreted the term "nominal price" in the Medicaid Drug Rebate Agreement as "any price less than 10% of the AMP in the same quarter for which the AMP is computed." MRA § I(s), 56 Fed. Reg. 7049, 7051 (Feb. 21, 1991); accord CMS, HHS, No. 14, Medicaid Drug Rebate Program Release, at 2 (1994). In accordance with the rebate agreement and subsequent CMS guidance, pharmaceutical companies could reasonably have decided not to include in their "best price" reports any prices discounted by more than 90 percent.

Yet again, however, FCA plaintiffs have converted such good-faith attempts to comply with a comprehensive regulatory scheme into allegations of fraud. In advocating for a narrower definition of the nominal price exception, these plaintiffs point to the legislative history of the rebate statute, which they argue shows that Congress intended to exclude those prices that "manufacturers offer to special purchasers, such as the sale of birth control pills for a penny a pack to Planned Parenthood." 136 Cong. Rec. S12954, S12962 (daily ed. Sept. 12, 1990). On the basis of this legislative history, the plaintiffs argue that sales with a commercial purpose do not come within the exception even if they would qualify as "nominal" under the Secretary's 10% interpretation. Referring to a dictionary definition, the plaintiffs also argue that the term "merely," as used in the rebate statute, should mean "without qualification." Thus, under their interpretation, prices that are "merely nominal in amount" are only those prices that are "nominal without qualification."

This argument has already prevailed in at least one FCA case. The United States District Court for the District of Nevada recently held that the phrase "'prices that are merely nominal in amount'" means "'all prices that are less than 10%

of the AMP, but without other qualifications'" or conditions.[9] *Nevada ex rel. Steinke* v. *Merck & Co.*, 432 F. Supp. 2d 1082, 1086 (D. Nev. 2006). Accordingly, the court refused to dismiss a state FCA action alleging that Merck & Co., Inc. had committed fraud by not including within its "best price" report the price of certain drugs it sold to hospitals at a 92% discount, even though Merck had quite reasonably interpreted the law to exclude those sales as falling within the nominal price exception.

The problem of ambiguous rules is of course not limited to the Medicaid Rebate Program. Another context in which pharmaceutical manufacturers have been charged with fraud under the FCA for allegedly violating ambiguous rules relates to the promotion of FDA approved drugs for additional therapies or uses that have not yet been approved by the FDA and are not included in the drug's label. Doctors are, in fact, allowed to use drugs "off-label" where there is scientific evidence to do so, and a large part of modern oncology therapy, for example, is done with off-label drugs.

While pharmaceutical manufacturers can provide relevant scientific evidence, they are not allowed to "promote" off-label uses of their drugs. This practice is known as "off-label" marketing. Creative FCA plaintiffs have argued that by promoting off-label uses of drugs in violation of the Food, Drug, and Cosmetic Act of 1938 ("FDCA"), manufacturers can "cause" the submission of false claims to the Medicare and Medicaid programs, which reimburse for some, but not all, off-label uses.

As the terminology suggests, a claim that a manufacturer has violated the FDCA depends on whether the manufacturer has "promoted" off-label uses of a drug. Not every statement by a manufacturer, however, is promotional, as the "FDA has

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[9] In so holding, the court failed to accord any deference to CMS's interpretation of the phrase "merely nominal in amount," as reflected in Section I(s) of the rebate agreement.

distinguished between those activities supported by manufacturers that are nonpromotional and otherwise independent from the substantive influence of the supporting manufacturer and those that are not," with only those activities in the latter category giving rise to a violation of the FDCA. Decision in *Washington Legal Found. v. Henney*, 65 Fed. Reg. 14,286, 14,287 (Mar. 16, 2000).

Unfortunately, the FDA's guidance as to which activities constitute impermissible "promotion" is notoriously inadequate. By way of example, almost ten years ago the agency published a Continuing Medical Education ("CME") guidance document in which it laid out an unwieldy twelve-pronged test for determining when a manufacturer's support of scientific and educational activities crosses the forbidden line into "promotion." See Final Guidance On Indus.-Supported Scientific Educ. Activity, 62 Fed. Reg. 64,074, 64,092-100 (Dec. 3, 1997). Many of the considerations outlined in the CME guidance are inherently vague.[10] Moreover, the factors listed are not exhaustive, and "[n]either the presence nor absence of any of the factors discussed in the CME guidance is necessarily dispositive in FDA's determination of whether it has adequate evidence to support a charge of misbranding." Letter from Margaret M. Dotzel, Assoc. Comm'r for Policy, FDA, to Daniel J. Popeo and Richard A. Samp 10 (Jan. 28, 2002), *available at* http://www.fda.gov/ohrms/dockets/dailys/02/Jan02/013002/01p-0250_pdn0001_01_vol2.pdf. Instead, the FDA has made clear that it will make decisions on a case-by-case basis, taking account of the totality of the circumstances. *Id.*

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[10] For example, the FDA considers whether: "the intent of the company and the provider is to produce an independent and promotional activity that is focused on educational content"; "the central theme is based on a single product marketed by the company or a competing product"; and "the title of the activity fairly and accurately represents the scope of the presentation."

Understandably frustrated by the lack of definitive guidance, manufacturers petitioned the FDA to issue additional guidance regarding manufacturer sponsorship of scientific and educational activities, but the FDA refused to do so. See *id.* (denying the petition and stating that "FDA has no current plan to expand or alter its CME guidance"). Manufacturers thus continue to face an unacceptable level of uncertainty as to which activities will be deemed illegal. As one court observed, "[a]fter six years' worth of briefs, motions, opinions, Congressional acts, and more opinions, the issue remains 100% unresolved, and the country's drug manufacturers are still without clear guidance as to their permissible conduct." *Washington Legal Found.* v. *Henney*, 128 F. Supp. 2d 11, 15 (D.D.C 2000). Indeed, the court viewed the argument that the FDA's off-label regulations are sufficiently clear as "a farce."[11] *Id.*

Not surprisingly, FCA plaintiffs have found ways to take advantage of the ambiguities in the regulations governing manufacturers' dissemination of information about off-label uses. These plaintiffs have brought suits alleging that manufacturers illegally promoted off-label uses of their drugs and

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[11] The FDA has similarly failed to issue adequate guidance relating to other aspects of the distinction between "promotion" and lawful dissemination of information. For example, the FDA generally permits companies to "disseminate information on unapproved uses in response to unsolicited requests for scientific information from health care professionals." Citizen Petition Regarding the FDA's Policy on Promotion of Unapproved Drugs and Devices, 59 Fed. Reg. 59,820, 58,823 (Nov. 18, 1994). The FDA, however, has failed to issue regulations addressing widespread questions in the industry as to the scope of this "unsolicited request" policy, such as which activities will be deemed a disqualifying "solicitation" of a request and whether the company's response must come from representatives of its medical department (as opposed to other personnel, such as sales representatives). In 1997, the FDA stated that it would issue a guidance document specifically addressing "Solicited and Unsolicited Requests for Information," Prescription Drug Advertising & Promotional Labeling; Development & Use of FDA Guidance Documents, 62 Fed. Reg. 14,912, 14,916 (Mar. 28, 1997), but it has yet to do so.

that their promotional activities caused doctors to submit false reimbursement claims to Medicare and Medicaid. In the absence of a clear rule that a reasonable interpretation of ambiguous rules cannot give rise to FCA liability, these plaintiffs have been able to force large FCA settlements notwithstanding the deep ambiguity of the off-label regulatory environment.[12]

There are many other examples of ambiguities in the federal health-care programs that have produced, or may yet produce, allegations of fraud under the FCA. As long as there is disagreement among the circuits as to whether FCA liability can attach to claims submitted to the government in accordance with an objectively reasonable interpretation of an ambiguous regulation, would-be FCA plaintiffs have every incentive to search out and exploit these ambiguities by filing FCA actions and leveraging uncertain legal exposure into settlements. There can thus be no doubt that the issue presented by this petition is a live question that has vitally important implications for the pharmaceutical industry.[13]

C. There Are Other Remedies Available To Ensure Compliance With Regulatory Requirements.

A rule limiting the ability of qui tam plaintiffs to pursue lucrative fraud claims for alleged violations of ambiguous regulations would not deprive the government of legitimate remedies. The government has at its disposal numerous tools to clarify ambiguous regulations. Indeed, the rule advocated herein would have the salutary effect of encouraging government agencies to utilize their notice and comment rulemaking procedures to clarify statutory and regulatory ambiguities.

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[12] *See, e.g.*, Press Release, U.S. Dep't of Justice, Warner-Lambert To Pay $430 Million To Resolve Criminal & Civil Health Care Liability Relating To Off-Label Promotion (May 13, 2004) (on file with author).

[13] The issue is also undoubtedly important to other sectors of the economy, such as defense contracting, that involve pervasive dealings with the government under complicated regulatory schemes.

In addition, the government has the means to require corrective action by pharmaceutical companies under a variety of circumstances. Most critically, when disputes arise over the meaning of regulations governing contractual relationships with the government, the government can invoke the remedial provisions of the contract at issue. Disputes over AMP and "best price," for example, all arise in the context of a contract – the Medicaid Drug Rebate Agreement – under which the government has a variety of remedial options. Perhaps most significantly, the government can terminate the agreement if it believes the manufacturer has violated the contract or there is other good cause. MRA § VIII(c), 56 Fed. Reg. at 7053. This is a significant stick for the government, for if an agreement is terminated, the manufacturer is prohibited from entering into another rebate agreement in the next quarter, in which case the manufacturer's drugs will not be eligible for Medicaid reimbursement. *Id.* § VIII(d). Moreover, if the government believes that a manufacturer has reported false information, it can invoke the penalty provisions of the agreement, which authorize the Secretary to impose a civil penalty of up to $100,000 for each item of false information. *Id.* § IV.

Similar contractual provisions apply to pharmaceutical manufacturers' reporting of prices to the Health Resources and Services Administration under the standard Pharmaceutical Pricing Agreement ("PPA") that governs manufacturers' relationship with the government in the 340B Program. The government can pursue a variety of remedies for perceived noncompliance or fraud. PPA § IV(c) (Mar. 24, 2005). It can "initiate the informal dispute resolution process," "require the Manufacturer to reimburse the entity for discounts withheld," or "terminate the Agreement." *Id.*

Likewise, when a pharmaceutical manufacturer submits claims to the government pursuant to a standard procurement contract, the government can pursue standard contractual remedies that apply generally to government contracts. Un-

der the Master Agreement governing pharmaceutical companies' provision of drugs to the VA, for example, if the government believes that a manufacturer is violating the terms of the contract, it can invoke the provisions of the Contract Disputes Act. Master Agreement § V(B). Pursuant to these provisions, the "contracting officer" for the government is "authorized . . . to decide or resolve all claims arising under or relating to a contract." 48 C.F.R. § 33.210. The contracting officer's decision is "final unless the Contractor appeals or files a suit as provided in the Act." *Id.* § 52.233-1(f). Thus, the government is able to resolve contract disputes in the first instance according to its preferred interpretation of the rules or regulations at issue. The onus is then on the contractor to challenge the government's decision through an internal appeals process or by filing suit in the Court of Federal Claims.

This case is thus *not* about whether an FCA defendant that acts on the basis of a reasonable interpretation of a regulation should be immune from all remedial measures if the government's contrary interpretation of the regulation is ultimately deemed correct. Rather, this case is *only* about whether an individual or entity should be held liable *for fraud* for submitting claims to the government in accordance with a reasonable interpretation of an ambiguous regulation. This Court should grant the petition to make clear that such conduct does not constitute fraud and therefore does not give rise to liability under the FCA.

II. THE DECISION BELOW IS WRONG, CREATES UNCERTAINTY, AND INCREASES THE INCENTIVE TO SETTLE MERITLESS FCA SUITS.

The decision below is plainly wrong. As petitioner has explained, allowing FCA liability to be premised upon claims submitted to the government in accordance with an objectively reasonable interpretation of ambiguous regulations is inconsistent with due process, the rule of lenity, the principle that ambiguous provisions should be construed against the drafter, and the federal courts' uniform interpretation of the

criminal False Claims Act. See Petition for Certiorari ("Pet.") 16-27. At bottom, these arguments all sound in a common theme: it is fundamentally unfair to hold someone liable *for fraud* when the sole basis for such liability is that he acted pursuant to a reasonable interpretation of an ambiguous regulation. Cf. *Walker Process Equip., Inc.* v. *Food Mach. & Chem. Corp.*, 382 U.S. 172, 176-77 (1965) (recognizing in another context that "an honest mistake" provides a "complete defense" to a claim of fraud); *United States* v. *Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) ("'Where there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim.'") (citation omitted).

Furthermore, the decision below creates an intolerable level of uncertainty. Those who submit claims for payment to the federal government pursuant to complex regulatory schemes must frequently make choices about how to comply with ambiguous provisions. The risk that each of these choices could give rise to treble damages plus substantial per-claim penalties could severely impair the efficiency of an industry. See Scheineson & Klinger, *supra*, at 11 (noting that it is "impossible to predict with any certainty which of today's accepted pharmaceutical industry practices may be challenged . . . as violative of fraud and abuse laws."). At very least, it substantially increases the cost of doing business with the government. See Henderson & Cassady, *supra*, at 107-08 (noting that FCA litigation "has caused confusion and uncertainty between pharmaceutical manufacturers and the providers and suppliers with whom they conduct federal health care program business").

The conflict that petitioner has demonstrated among the courts of appeals, see Pet. 9-16, needlessly exacerbates the uncertainty companies face when deciding whether to litigate or settle FCA actions premised upon the alleged violation of ambiguous regulations. Manufacturers sued in circuits that

have not addressed the issue must attempt to divine the applicable legal rule in the face of conflicting decisions from other circuits. In the absence of a clear and uniform rule, the obvious incentive is to settle such cases in order to gain certainty and avoid exposure to the FCA's draconian financial penalties. See, *e.g.*, Scheineson & Klinger, *supra*, at 6 (noting that "the FCA provides a substantial economic incentive not only for employees, competitors, and others to report allegedly fraudulent activities by pharmaceutical companies to DOJ, but also for DOJ to pursue such actions in hopes of forcing manufacturers to resolve matters rather than face the catastrophic economic exposure brought by an adverse ruling at trial").

Thus, if the conflict is allowed to persist, companies will continue to face pressure to pay huge amounts to settle FCA actions despite their insistence that they have done nothing illegal or fraudulent. See, *e.g.*, *SmithKline Whistleblowers Get $42.3 Million*, Pa. L. Wkly., Apr. 20, 1998, at 1 (noting that, even after paying $325 million, SmithKline "denied the allegations, saying the violations were unintentional and the result of ambiguities in regulations and guidelines"). Moreover, given the substantial sums involved in many of these settlements, would-be relators will continue to have a substantial incentive to exploit ambiguities in the hopes of forcing a lucrative settlement. See Henderson & Cassady, *supra*, at 116, 119, 121, 123 (reporting that the relators' recoveries in four major settlements were $31.6 million, $24.64 million, $47.5 million, and $34.2 million).

The overwhelming incentive to settle these cases also provides a compelling reason for the Court to grant the petition in this case. Settlements in this area have short-circuited the judicial process, preventing courts from ruling on the merits of the claims and potential defenses. Consequently, the question presented by the petition is (to borrow a phrase from another context) capable of repetition yet evading review. The decision below is exceptional in that the court not only con-

fronted the question, but also resolved it in a way that squarely presents it for this Court's review. See Petr's App. 12a (recognizing that "the regulatory language . . . was ambiguous," but nonetheless allowing plaintiff's FCA action to proceed). The Court should thus take this opportunity to resolve the issue and thereby provide a measure of certainty to companies faced with FCA claims.

Finally, the significant sums paid by pharmaceutical companies to settle these dubious FCA actions, as well as the risk that qui tam relators will find more ambiguities to exploit, are a significant cost of doing business. As such, they inevitably diminish the resources available for productive activities such as the research and development of new drugs. Pharmaceutical manufacturers pay a significant amount of money to participate in and comply with government programs. They should not be required to pay a further premium to finance the settlement of extortionate lawsuits that seek to convert their reasonable attempts to comply with ambiguous regulations into fraud.

For each of these reasons, the Court's review is urgently required to resolve the conflict among the circuits and to make clear that a reasonable interpretation of an ambiguous statute or regulation cannot give rise to liability for fraud under the FCA.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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October 2, 2006

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No. 06-152

IN THE

Supreme Court of the United States

R & F PROPERTIES OF LAKE COUNTY, INC.,
Petitioner,

v.

UNITED STATES OF AMERICA *EX REL.* KARYN L. WALKER,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

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MOTION FOR LEAVE TO FILE BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

Pursuant to Rule 37.2 of the Rules of this Court, the Washington Legal Foundation (WLF) respectfully moves for leave to file the attached brief as amicus curiae in support of Petitioner. Counsel for Petitioner has consented to the filing of this brief. Counsel for Respondent has refused consent because she believes the petition should not be granted.

WLF is a non-profit public interest law and policy center based in Washington, D.C., with supporters in all 50 states. WLF devotes a substantial portion of its resources

to promoting a limited and accountable government, supporting the free enterprise system, and opposing abusive enforcement actions and civil litigation by the government and private litigants. WLF regularly participates in important constitutional and statutory litigation raising these issues.

More pertinently, WLF has appeared before this Court and other federal courts in cases raising significant issues regarding the application of the *qui tam* provisions of the False Claims Act (FCA). *See, e.g.*, *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939 (1997); *Boeing Co. v. United States ex rel. Kelly*, *cert. denied*, 510 U.S. 1140 (1994); *Riley v. St. Luke's Episcopal Hospital*, 196 F.3d 514 (5th Cir. 1999).

In addition, WLF's Legal Studies Division produces and distributes legal public policy publications on numerous topics, including the False Claims Act. *See, e.g.*, J. Andrew Jackson & Edward W. Kirsch, THE *QUI TAM* QUAGMIRE: UNDERSTANDING THE LAW IN AN ERA OF AGGRESSIVE EXPANSION (WLF Monograph) (1998); John T. Boese, *New False Claims Law Incentives Pose Risk To Contractors And States* (WLF Working Paper) (June 2006); J. Andrew Jackson, *A Law Gone Rogue: Time To Return Fairness To The False Claims Act* (WLF Legal Backgrounder) (Dec. 16, 2005).

WLF submits that over the last two decades, the 1986 amendments to the FCA have spawned abusive punitive litigation against businesses, both large and small, to the detriment of those businesses, their employees, their shareholders, and the public at large. The decision of the court of appeals below is particularly troubling inasmuch as the punitive provisions of the FCA are predicated on the

petitioner's reasonable interpretation of confusing and ambiguous regulations or contract provisions. WLF believes that it can bring an additional perspective to the issue presented in this case and assist the Court in deciding whether to grant the petition.

For the foregoing reasons, WLF respectfully requests that it be allowed to participate in this case by filing the attached brief as amicus curiae.

Respectfully submitted,

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Date: October 2, 2006

QUESTION PRESENTED

Whether liability under the civil False Claims Act, 31 U.S.C. §§ 3729-3733, can be based on a defendant's reasonable interpretation of an ambiguous regulation or contractual provision?

TABLE OF CONTENTS

TABLE OF AUTHORITIES v

INTERESTS OF AMICUS CURIAE 1

REASONS FOR GRANTING THE PETITION 2

I. THE PETITION RAISES AN IMPORTANT QUESTION OF FEDERAL LAW THAT SHOULD BE SETTLED BY THIS COURT . . . 3

A. FCA Liability Was Greatly Expanded in 1986 3

B. FCA Actions Based on Complex and Ambiguous Regulations and Contract Provisions Encourage Frivolous *Qui Tam* Suits That Do Not Deter Fraud or Promote the Public Interest 5

C. The Court of Appeals' Expansive Approach to FCA Liability Neither Deters Fraud nor Promotes the Public Interest 8

D. The Punitive Features of the FCA, and Its Severe Collateral Sanctions, Are Disproportionate When Imposed Under Ambiguous Regulations and Contract Provisions 10

E. The Rule of Lenity Should Be Applied in FCA Cases Involving Ambiguous Regulations and Contract Provisions 13

CONCLUSION 15

TABLE OF AUTHORITIES

Page

Cases:

Austin v. United States, 509 U.S. 602 (1993) 14
Babbitt v. Sweet Home Chapter of Communities for a Great Or., 515 U.S. 687 (1995) 14
Buckley v. Valeo, 424 U.S. 1 (1976) 9
Cook County, Ill. v. United States ex rel. Chandler, 538 U.S. 119 (2003) 11
H.B. Mac, Inc. v. United States, 36 Fed. Cl. 793 (1996) 6
Hughes Aircraft Co. v. United States ex rel. Schumer, 520 U.S. 939 (1997) 8
In re Cardiac Devices Qui Tam Litig., 221 F.R.D. 318 (D. Conn. 2004) 6
Ladner v. United States, 358 U.S. 169 (1958) 14
Liparota v. United States, 471 U.S. 419 (1985) . . 13-14
Morrison v. Olson, 487 U.S. 654 (1988) 9-10
Rewis v. United States, 401 U.S. 808 (1971) 14
Staples v. United States, 511 U.S. 600 (1994) 14
United States ex rel. Lissack v. Sakura Global Capital Mkts., Inc., 377 F.3d 145 (2d Cir. 2004) 6
United States ex rel. Schuhardt v. Wash. Univ., 228 F. Supp. 2d 1018 (E.D. Mo. 2002) 6
United States v. Data Translation, Inc., 1984 F.2d 1256 (1st Cir. 1992) 6-7
United States v. Newport News Shipbuilding, Inc., 276 F. Supp. 2d 539 (E.D. Va. 2003) 4
United States v. One 1973 Rolls Royce, 43 F.3d 794 (3d Cir. 1994) 14
United States v. Thompson/Ctr. Arms Co., 504 U.S. 505 (1992) 14
Vt. Agency of Natural Res. v. United States ex rel. Stevens, 529 U.S. 765 (2000) 10-11

Statutes, Regulations, and Legislative Materials:

21 U.S.C. § 881(a) 14
31 U.S.C. § 3729(a) 4, 13
31 U.S.C. § 3729(b) 4
31 U.S.C. § 3730(c) (1982) 4
31 U.S.C. § 3730(d)(1) 4
31 U.S.C. § 3730(d)(2) 4
31 U.S.C. § 3730-3733 3
42 U.S.C. § 1320(a) 11
42 C.F.R. § 1001 11
48 C.F.R. § 9.406-2 11
S. Rep. No. 99-345 (1986) *reprinted in* 1986 U.S.C.C.A.N. 5266 3

Miscellaneous:

Pamela H. Bucy, *Information as a Commodity in the Regulatory World,* 39 Hous. L. Rev. 905 (2002) 13
Ben Depoorter & Jef De Mot, *Whistle Blowing: An Economic Analysis of the False Claims Act,* 14 Sup. Ct. Econ. Rev. 135 (2006) 10
Michael Lawrence Kolis, *Comment, Settling for Less: The Department of Justice Command Performance Under the 1986 False Claim Amendments Act*, 7 Admin. L. J. Am. U. 409 (1993) 8
Joan H. Krause, *Promises to Keep: Health Care Providers and the Civil False Claims Act,* 23 Cardozo L. Rev. 1363 (2002) 11-12
Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. Ann. Surv. Am. L. 241 (2004) 5
John B. Reiss & William M. Janssen, *Your Business in Court*, FDLI Update, Mar./Apr. 2005 12

Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case For Expanding the Role of Administrative Agencies,* 91 Va. L. Rev. 93 (2005) 9

Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement,* 51 Ala. L. Rev. 239 (1999) . . . 12

Christopher Yukins, *et al., International Procurement,* 40 Int'l Law. 337 (2006) 12

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS AMICUS CURIAE IN SUPPORT OF PETITIONER

INTERESTS OF AMICUS CURIAE

The interests of amicus curiae Washington Legal Foundation (WLF) are set forth in the motion accompanying this brief.[1]

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF, contributed monetarily to the preparation and submission of this brief.

REASONS FOR GRANTING THE PETITION

This case raises an issue of exceptional and national importance: whether the False Claims Act (FCA) may be used to punish persons for making claims for payment from the government when the allegedly "false" or "fraudulent" claims are based on reasonable interpretations of ambiguous agency regulations or contract provisions. Here, the FCA suit arose under complex Medicare billing regulations that the court of appeals recognized were ambiguous. *See* Pet. App. at 5 ("We agree that the regulatory language in effect . . . was ambiguous.").

By reversing the district court's grant of summary judgment for the petitioner and allowing the suit to proceed, the Eleventh Circuit improperly expanded the FCA beyond the parameters established by Congress. Permitting FCA actions to go to trial in this and other cases based on ambiguous agency regulations, directives, manuals, and contract provisions, undermines the FCA as a credible deterrent against fraud, encourages frivolous and costly lawsuits, and raises grave due process concerns by unfairly imposing substantial penalties in a way Congress never intended.

As the petition makes clear, the Eleventh Circuit's ruling not only is wrong, but also is in conflict with the decisions of other circuits and lower federal courts. Pet. at 9-21. Accordingly, this case, which presents a pure question of law, is an ideal vehicle for the Court to settle the important question of whether a reasonable interpretation of an ambiguous regulation or contract

provision can give rise to an FCA claim.[2]

I. THE PETITION RAISES AN IMPORTANT QUESTION OF FEDERAL LAW THAT SHOULD BE SETTLED BY THIS COURT

A. FCA Liability Was Greatly Expanded in 1986

The FCA permits private citizens to bring a "*qui tam*" suit in the name of the United States, and allows the initiator of the suit, the "relator," to share in the proceeds of any recovery. *See* 31 U.S.C. §§ 3730-3733. Congress amended the FCA in 1986 to make it easier for relators and the United States to litigate cases, expanding it to "reach all fraudulent attempts to cause the Government to pay out sums of money or to deliver property or services." S. Rep. No. 99-345, at 9 (1986), *reprinted in* 1986 U.S.C.C.A.N. 5266, 5274. Among the principal problems prompting the passage of the 1986 amendments was the lack of a credible deterrent to fraudulent conduct: "Fraud is perhaps so pervasive and, therefore, costly to the Government due to a lack of deterrence." *Id.* at 3, *reprinted in* 1986 U.S.C.C.A.N. at 5268.

The 1986 amendments deterred fraud in several ways. First, the 1986 amendments substantially increased financial incentives for *qui tam* relators to bring suit, particularly in cases where the United States elects not to intervene.[3] Second, the 1986 amendments lowered the

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[2] While WLF submits that the conflict among the circuits on the question presented alone warrants review, WLF will focus its brief on the legal and policy issues implicated by the question presented that further underscore the importance of this case.

[3] Though *qui tam* lawsuits may be initiated by private citizens, the Department of Justice may choose to participate as of right in a

standard of proof to establish an FCA violation. To create liability, a relator need not prove intent to defraud, but only a knowing submission of a false claim. Under the FCA, "knowing" means: 1) actual knowledge of the falsity of information, 2) acting with conscious ignorance as to the truth or falsity of the information, or 3) acting with reckless disregard as to the truth or falsity of the information. 31 U.S.C. § 3729(b).[4] Third, the 1986 amendments imposed treble damages and penalties. 31 U.S.C. § 3729(a).

An FCA defendant faces even more severe collateral penalties, such as debarment from government contracting or, in cases such as this, exclusion from the Medicare

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relator-initiated action. *See* 31 U.S.C. §§ 3730-3733. Prior to the 1986 amendments, relators' awards were limited to 10 percent in cases of government intervention, and 25 percent in non-intervention cases. *See* 31 U.S.C. § 3730(c) (1982). Today, when the government intervenes in a *qui tam* action, the relator's share in a recovery is at least 15 percent but not more than 25 percent of the proceeds. *See* 31 U.S.C. § 3730(d)(1). If the United States *does not* join in the suit, a relator's recovery *increases* to between 25 and 30 percent of the proceeds. *See* 31 U.S.C. § 3730(d)(2).

While relators hope that the Department of Justice will intervene and give them a free litigation ride, even when the Department declines to do so, relators have many incentives to continue to press tortured claims based upon ambiguous or complex regulations. In addition to reaping a higher percentage of the settlement, the *qui tam* relator can be awarded reasonable expenses, attorneys' fees, and costs. *Id.* These financial rewards have created a powerful private litigation incentive, which has led to a rapid proliferation of FCA actions and recoveries over the last 20 years, and forced settlements of cases of dubious merit.

[4] *See United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 566 (E.D. Va. 2003) (allowing an FCA suit to proceed under an admittedly ambiguous regulation because a fact finder nonetheless "might conclude" that the defendant acted with reckless disregard as to the permissibility of charges under the regulation).

programs, if FCA liability is found. These collateral penalties are a virtual death sentence for a business and its employees.

FCA litigation exploded after the 1986 amendments. According to Department of Justice statistics, combined settlements and judgments arising from *qui tam* lawsuits skyrocketed from $390,431 in 1988 to $1,141,743,736 in 2005.[5] Of these, relators' award shares increased from $97,388 in 1988 to $166,375,477 in 2005.[6] Notably, in cases where the United States *declined* to intervene, relators' award shares multiplied more than 700 times.[7]

B. FCA Actions Based on Complex and Ambiguous Regulations and Contract Provisions Encourage Frivolous *Qui Tam* Suits That Do Not Deter Fraud or Promote the Public Interest

Highly complex regulations and contract provisions are a ripe breeding ground for frivolous *qui tam* suits. As one federal prosecutor acknowledged, "[t]he passage of time seldom brings a simplification or reduction of law, regulation, guidance, and informal advice; rather, accretion and increasing complexity are the characteristics of any mature bureaucratic system. Complexity in regulation feeds on itself." Joan H. Krause, *Regulating, Guiding, and Enforcing Health Care Fraud*, 60 N.Y.U. Ann. Surv. Am. L. 241, 275 (2004) (quotation marks and citations omitted). This phenomenon has become increasingly evident in FCA litigation, as illustrated by judicial observations regarding

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[5] 2006 Justice Department Qui Tam Statistics, *available at* http://www.taf.org/fcastatistics_2006.pdf.

[6] *Id.*

[7] *Id.*

the complexity of regulations giving rise to *qui tam* cases across many sectors, including health care,[8] government contracting,[9] and federal taxation.[10]

These ambiguous regulations often result in FCA actions that stretch the statute beyond recognition. *United States v. Data Translation, Inc.*, 984 F.2d 1256 (1st Cir. 1992), is a particularly egregious example. There, the government brought an FCA suit against a contractor based on its offer to sell computer circuit boards. The purported "false claim" arose from Data Translation's alleged failure to disclose all of the prices at which it had sold the computer board to commercial customers, supposedly contrary to General Services Administration procurement policies and disclosure requirements. Then Chief Judge Breyer found the government's theory of liability to be almost incredible:

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[8] *See In re Cardiac Devices Qui Tam Litig.*, 221 F.R.D. 318, 354 (D. Conn. 2004) ("Clearly, the Medicare reimbursement regulations would qualify as highly technical and complex."); *see also United States ex rel. Schuhardt v. Wash. Univ.*, 228 F. Supp. 2d 1018, 1026 (E.D. Mo. 2002) ("The teaching physician reimbursement regulations concern a regulatory program, under Medicare, that is without a doubt complex and highly technical.") (quotation marks and citations omitted).

[9] *See H.B. Mac, Inc. v. United States*, 36 Fed. Cl. 793, 816 (1996) (discussing the "complex, poorly-worded, [small disadvantaged business] regulations relating to control of a business for purposes of determining whether plaintiff knowingly misrepresented or willfully disregarded its status and, thereby, attempted to perpetrate a fraud upon the United States").

[10] *See United States ex rel. Lissack v. Sakura Global Capital Mkts., Inc.*, 377 F.3d 145, 147 (2d Cir. 2004) (FCA action concerning a "highly complex financial scheme involving tax-exempt state and local government (municipal) bonds . . . which lies at the intersection between finance and tax law").

> We concede the circumstance to which the Government points with pride, namely, the exhaustiveness of the disclosure that the language literally demands. But, it is that very circumstance that creates a problem. Exaggerating to explain our point, we find the Government's interpretation a little like that of, say, a park keeper who tells people that the sign "No Animals in the Park" applies literally and comprehensively, not only to pets, but also to toy animals, insects, and even chicken sandwiches. If one met such a park keeper, one would find his interpretation so surprisingly broad that one simply would not know what he really meant or what to do. We do not mean to say this farfetched example directly applies here. But, the example . . . may help the reader understand why we think a literal reading of the disclosure form creates ambiguity and incomprehensibility, and why we conclude that no reasonable person, negotiating with GSA negotiator Carr, could have believed that the Government really wanted the complete and total disclosure for which the language seems to ask.

Id. at 1261. *Data Translation* illustrates how ambiguous and confusing statutory or regulatory requirements can easily spawn contrived FCA actions based on a defendant's reasonable interpretation of those requirements, rather than on fraudulent acts that Congress intended to deter and punish. To allow such FCA actions runs the risk that the substantial punitive and collateral penalties under the FCA will be inconsistently and unfairly imposed.

C. The Court of Appeals' Expansive Approach to FCA Liability Neither Deters Fraud nor Promotes the Public Interest

As this Court has noted, "*qui tam* relators are . . . motivated primarily by prospects of monetary reward rather than the public good . . . [and] are thus less likely than is the Government to forgo an action arguably based on a mere technical noncompliance . . . that involved no harm to the public fisc." *Hughes Aircraft Co. v. United States ex rel. Schumer*, 520 U.S. 939, 949 (1997). Where ambiguous regulations and contract provisions provide a turn-key platform for an enormous windfall, financial motivation can lead to a rapid proliferation in FCA claims that neither deter fraud nor promote the public interest. This is best evidenced by the fact that the Department of Justice only intervenes in approximately 20 percent of *qui tam* actions.[11]

The proliferation of private FCA suits based on ambiguous regulations and contract provisions is at odds with the fraud deterrent and public interest objectives of the FCA for several reasons. First, private plaintiffs "may be insufficiently sensitive to the litigation costs of their suits (including the drain on judicial resources) . . . [and] may be less sensitive than government agencies to the economic and social costs of particular enforcement actions, such as the disruptive impact on affected communities, relative to the social benefits of such actions." Matthew C. Stephenson, *Public Regulation of Private Enforcement: The Case for Expanding the Role of Administrative Agencies*, 91

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[11] Michael Lawrence Kolis, Comment, *Settling for Less: The Department of Justice's Command Performance Under the 1986 False Claim Amendments Act*, 7 Admin. L.J. Am. U. 409, 412 n.13 (1993).

Va. L. Rev. 93, 114-15 (2005). Private litigants also are likely to be less sensitive to the possibility that a *qui tam* action may result in the termination of a company's ability to do business with the government, resulting in bankruptcy for the company and the near certain loss of jobs for employees having no part in the false claims.

Moreover, unlike federal prosecutors, private relators have no accountability for the social and economic impact of their decisions to initiate *qui tam* actions. Prosecutorial discretion, of course, is "an integral part of the American system of government, and executive agencies are accountable to the electorate for their exercise of this discretion through the President and, more indirectly, through congressional oversight." *Id.* at 119. For that reason, the United States Attorneys' Manual stresses that "the manner in which Federal prosecutors exercise their decision-making authority has far-reaching implications, both in terms of justice and effectiveness in law enforcement and in terms of consequences for individual citizens." USAM, 9-27.000, Principles of Federal Prosecution.[12]

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[12] The lack of executive involvement in the prosecution of private *qui tam* cases, coupled with the lack of accountability to the public, raises a question as to the constitutionality of the private enforcement provisions of the FCA under both the Appointments Clause and the Take Care Clause of the Constitution. *See, e.g.*, *Buckley v. Valeo*, 424 U.S. 1, 140 (1976) (holding that Appointments Clause of the Constitution prohibits vesting "primary responsibility for conducting civil litigation . . . for vindicating public rights" in persons not properly appointed under the Appointments Clause); *Morrison v. Olson*, 487 U.S. 654, 696 (1988) (instructing the President, pursuant to the Take Care Clause, to retain substantial control over any person charged with executive functions). This question, while not raised here, was reserved by the Court in *Vermont Agency of Natural*

Prosecutorial discretion also has a substantial impact on the deterrence of fraud and the overall effectiveness of the FCA regime. For instance, the Department of Justice "has an interest not simply in prosecution and punishment but also in generating goodwill to persuade companies to improve monitoring procedures. In some cases, leniency by the government will promote goodwill and better future behavior, especially where there is an educational component." Ben Depoorter & Jef De Mot, *Whistle Blowing: An Economic Analysis of the False Claims Act*, 14 Sup. Ct. Econ. Rev. 135, 154 (2006). Stated differently, sometimes full-scale litigation under the FCA is not the best tool to deter fraud in a manner consistent with the public interest. This is particularly true given the magnitude of the penalties that confront a business that faces liability-triggering ambiguous regulations.

D. The Punitive Features of the FCA, and Its Severe Collateral Sanctions, Are Disproportionate When Imposed Under Ambiguous Regulations and Contract Provisions

This Court has recognized that the FCA's damage scheme is punitive in nature. *See Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 785-86 (2000). Moreover, "the very idea of treble damages [present in the FCA] reveals an intent to punish past, and to deter future, unlawful conduct, not to ameliorate the liability of wrongdoers." *Id.* at 786 (quotation marks and citations omitted); *see also Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 130-32 (2003) (acknowledging punitive features under FCA damages scheme).

Resources v. United States ex rel. Stevens, 529 U.S. 765 (2000).

In addition to this punishment, entities found liable under the FCA also face collateral penalties that may greatly exceed those imposed by the statute. For example, the Federal Acquisition Regulations provide that government contractors may be debarred or suspended from obtaining or performing government contracts if they are found liable for an FCA violation. *See* 48 C.F.R. § 9.406-2 (2006). For companies doing substantial business with the government, this can be a death sentence.

For health care providers, a similar calamitous fate awaits. A health care provider may be excluded from the Medicare program under Title IX of the Social Security Act for violation of the FCA. *See* 42 U.S.C. § 1320(a); 42 C.F.R. § 1001 (2006). As the federal government pays for approximately one half of the health care costs in the United States, exclusion from federal health care programs can drive a provider into an operating loss. Moreover, because health care providers, unlike defense contractors, tend to submit a large number of small claims each year, statutory penalties "can reach astronomical proportions."[13] Joan H.

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[13] The FCA provides statutory penalties of $5,500 to $11,000 per claim, regardless of the size of the claim. 31 U.S.C. § 3729(a); *Civil Monetary Penalties Inflation Adjustment*, 64 Fed. Reg. 47,099 (Aug. 30, 1999). Indeed, when individual claim value – and therefore actual damages – is very low, relators and the Department of Justice focus upon these disproportionately large penalties. For a medical provider that routinely submits a large number of small claims, these penalties may quickly escalate. Similarly, a government contractor selling services through the General Services Administration's Federal Supply Schedule may process hundreds or thousands of government sales per day. FCA liability arising under those sales can result in heavy penalties for seemingly minor violations. *See* Christopher Yukins *et al.*, *International Procurement*, 40 Int'l Law. 337, 346 (2006).

Krause, *Promises to Keep: Health Care Providers and the Civil False Claims Act*, 23 Cardozo L. Rev. 1363, 1370 (2002). In fact, many health care providers are forced to settle rather than challenge an FCA action and expose themselves to the draconian punitive and collateral penalties under the FCA. Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 Ala. L. Rev. 239, 241-43 (1999). Other commentators have observed that "[b]ecause the False Claims Act permits fines of up to three times the amount of the claim – and penalties of between $5,500 and $11,000 per claim – penalties can add up quickly to billions of dollars, [providing] an enormous 'hammer' with which to exact settlements." John B. Reiss & William M. Janssen, *Your Business in Court*, FDLI Update, Mar./Apr. 2005, at 4.

In the health care context, the threat of penalty and exclusion can have an even greater adverse social impact – doctors and other health care providers will simply refuse to participate in Medicare or any similar government reimbursement program and limit their practices to non-governmental third-party payors (insurance companies) and more wealthy private payors. The elderly and those less fortunate will suffer most.

To be sure, the combination of treble damages and collateral penalties forms a powerful deterrent against fraud. As one commentator notes, "[t]he sanctions imposed in [punitive civil] actions [such as the FCA] can have enormous deterrent impact for they impose large penalties and can lead to imposition of collateral sanctions, such as exclusion from conducting future business or from one's profession altogether." Pamela H. Bucy, *Information as a Commodity in the Regulatory World*, 39 Hous. L. Rev. 905,

918 (2002) (footnote omitted). But the unfair or inconsistent application of these penalties may result in manifest injustice because individuals and companies do not have a clear statement of what kind of conduct is prohibited under the law. This problem now has become far more acute, thanks to the proliferation of FCA actions such as this one seeking to punish individuals and companies for honest and reasonable interpretations of ambiguous statutes, regulatory schemes, contract provisions, guidance, and directives.

E. The Rule of Lenity Should Be Applied in FCA Cases Involving Ambiguous Regulations and Contract Provisions

Modern FCA actions brought under the unfair and inconsistent application of highly complex regulatory schemes and contract provisions have the potential to bankrupt those found liable. Given this potential, and the mushrooming of FCA litigation during the last 20 years, the regulated community and government contractors should not be subjected to the unfair application of the FCA. As a matter of due process, they should be given clear warning of what conduct might give rise to FCA liability.

This Court frequently has invoked the rule of lenity to require that ambiguities in criminal statutes be resolved in favor of defendants. *See Liparota v. United States*, 471 U.S. 419, 425 (1985) (finding it appropriate to apply the rule of lenity to avoid "criminaliz[ing] a broad range of apparently innocent conduct"); *see also Staples v. United States*, 511 U.S. 600 (1994); *Rewis v. United States*, 401 U.S. 808 (1971); *Ladner v. United States*, 358 U.S. 169 (1958) (recognizing rule of lenity). The Court also has applied the rule in the civil context. *See United States v.*

Thompson/Ctr. Arms Co., 504 U.S. 505, 517-19 & n.10 (1992) (plurality opinion) (employing the rule of lenity to interpret "a tax statute . . . in a civil setting" because the statute "has criminal applications"); *id.* at 519 (Scalia, J., concurring in judgment) (also invoking the rule of lenity); *see also Austin v. United States*, 509 U.S. 602, 619-22 (1993) (holding that civil drug forfeitures under 21 U.S.C. § 881(a)(4), (7) are punishment under the Eighth Amendment's Excessive Fines Clause); *United States v. One 1973 Rolls Royce*, 43 F.3d 794, 819 (3d Cir. 1994) (Section 881(a)(4) forfeiture "is punitive and quasi-criminal in nature.").

The rule of lenity rests on two fundamental due process principles. First, that "a fair warning should be given to the world in language that the common world will understand, of what the law intends to do if a certain line is passed." *Babbitt v. Sweet Home Chapter of Communities for a Great Or.*, 515 U.S. 687, 704 n.18 (1995) (quotation marks and citations omitted). Second, that "legislatures and not courts should define criminal activity." *Id.*

The first of these principles, clear and fair warning, is necessary to ensure that the penalties under the FCA are imposed fairly, and that the statute's deterrent effect is preserved. The second concept is equally important: that Congress be given the opportunity to define the scope and reach of the FCA – not the courts, and certainly not relators motivated primarily by financial gain.

Complex and ambiguous regulatory and contract provisions are common in a wide variety of regulated industries, from health care to government contracting. Businesses operating within these industries, as well as government regulators, are constantly required to make

reasoned judgments about the meaning and application of these regulations and contract provisions. While there is no question that honest disagreements will arise under these complex and ambiguous regulations and provisions, and that there are non-punitive methods to resolve those disagreements, there is also no question that such disagreements are a far cry from fraud. The decision below contravenes the rule of lenity and would improperly allow use of the FCA to punish unfairly government contractors or health care providers that guessed wrong.

CONCLUSION

For the foregoing reasons and those presented by Petitioner, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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